U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6861–6900

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and including, in one case, the entry of a decree of injunction; and (2) a criminal proceeding which was terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceeding was against the *firm* charged to be responsible for the violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *January 7, 1963.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 6874, 6895; an imitation of, and sale under name of, another drug, No. 6875; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6863, 6894; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6863, 6874, 6894.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6861–6900

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in whole or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article was for use by man and contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulations designated as, habit forming, and its label failed to bear the statement "Warning—May be habit forming."; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6861. Entoquel syrup and Entoquel with Neomycin syrup. (F.D.C. No. 46218. S. Nos. 20–908/9 R.)

QUANTITY: 25 6-oz. btls. of *Entoquel syrup* and 32 6-oz. btls. of *Entoquel with Neomycin syrup*, at Cleveland, Ohio, in possession of Grey Drug Stores, Inc.

SHIPPED: 2–6–61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: (Btl.) "Entoquel Syrup (Thihexinol Methyl Bromide) Caution: * * * White Laboratories, Inc., Kenilworth, New Jersey. Dosage * * * Each Teaspoon (5 cc) contains * * * Thihexinol Methyl Bromide–5 mg. Alcohol –1%" and "Entoquel with Neomycin Syrup Caution: * * * White Laboratories, Inc. * * * Dosage: * * * Each teaspoon (5 cc) contains * * * Thihexinol (Entoquel)–5 mg. Neomycin (from the sulfate)–50 mg. Alcohol–0.5%."

ACCOMPANYING LABELING: Promotional form letter entitled "Dear Doctor" and leaflet entitled "Are opiates now outmoded in pediatric diarrhea?"

LIBELED: 8-1-61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article "acts almost exclusively to inhibit gastrointestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine like effects when given in the recommended dosage" and that the "only side effect noted was a mild, more or less transient flushing of the skin"; will successfully treat diarrhea, which threatens pediatric patients, without side effects; and stop diarrhea rapidly, without side effects; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and it was not exempt from the requirement since the promotional material for the new drugs was not the same as, or substantially the same as, the labeling authorized by the effective new drug applications; and 505(a)—the effective new drug application did not apply to the conditions for which the articles were promoted to the medical profession, namely, for the treatment of complications of severe pediatric diarrhea-dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen, and constant crying; nonspecific digestive upsets and for nausea and vomiting.

DISPOSITION: 10-18-61. Default—destruction.

DRUG FOR VETERINARY USE

6862. Zoamix medicated feed premix. (F.D.C. No. 46851. S. Nos. 6-468 T, 7-342 T.)

QUANTITY: 63 50-lb. bags at Augusta, Maine.

SHIPPED: 10-25-61 and 11-28-61, from Newark, N.J.

LABEL IN PART: "ZOAMIX A Premix Medicated * * * For Chickens Only. Active Ingredients: Zoalene (3.5-Dinitro-O-Toluamide) 25%."

RESULTS OF INVESTIGATION: The manufacturer of the article had filed a new drug application which was effective with respect to shipments of the article made to feed manufacturers who had filed effective supplemental new drug applications covering the use of the article in finished feeds. Investigation revealed that the article had been purchased by a dealer at Augusta, Maine for use in the feeds which he manufactured but that such dealer had not filed a supplemental new drug application which was effective for such use.

LIBELED: 12-13-61, Dist. Maine.

CHARGE: 505(a)—the article was a new drug, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 1-3-62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6863. Various prescription drugs. (F.D.C. No. 46109. S. Nos. 50-529/33 R, 50-535/8 R.)

QUANTITY: 6,431 tablets and capsules and 70 clips of vials, btls., and packs, at Denver, Colo., in possession of Earl Meyer Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Professional Package," "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample–Not To Be Sold," and "Professional Specimen."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by the dealer into containers having labels bearing brand names indicative of manufacture outside the State of Colorado, and quantities of nonrepacked physicians' samples of prescription drugs.

LIBELED: 7–27–61, Dist. Colo.; amended libel 8–25–61.

CHARGE: 502(a)—while held for sale, the statements "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample–Not To Be Sold," "Professional Specimen" and similar wording on the labels of a number of the articles of drug were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not then intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the repacked articles of drug failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(f)(1)—the labeling of the repacked articles of drug failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as required by regulations; and 503(b)(4)—the repacked articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–6–61. Default—destruction.

6864. Elixir phenobarbital. (F.D.C. No. 46471. S. Nos. 45–523/4 R.)

QUANTITY: 100 cases, 4 1-gal. btls. each, at Atlanta, Ga.

SHIPPED: Between 2–8–61 and 4–3–61, from Greenville, S.C., by Cambridge Pharmaceuticals.

LABEL IN PART: (Some btls.) "Elixir Phenobarbital Hyoscyamine and Hyoscine Hydrobromide and Atropine * * * Each 5 cc contains: Hyoscyamine Hydrobromide 0.1037 mg. Hyoscine Hydrobromide 0.0065 mg. Atropine Sulfate 0.0194 mg. Phenobarbital 16 mg. Alcohol 20% Mfg. for Grady Hospital, Atlanta, Georgia Mfg. by Cambridge Pharmaceuticals, 117 Cleveland Street, Greenville, S.C." and (some btls.) "Elixir Phenobarbital and Belladonna Alkaloids (NF) Each 5 cc contains: 16.2 mg. Phenobarbital (Warning: May be habit forming) 0.1037 mg. Hyoscyamine Sulfate 0.0194 mg. Atropine Sulfate 0.0865 mg. Hyoscine Hydrobromide 20% Alcohol Caution: * * * Mfg. for Grady Memorial Hospital * * * Atlanta, Georgia Mfg. by Cambridge Pharmaceuticals, 117 Cleveland Street Greenville, S.C."

RESULTS OF INVESTIGATION: Analysis showed that all bottles of the article contained less than 10 percent of the labeled amount of the belladonna alkaloids (calculated as atropine sulfate). The label of some bottles bore the notation NF, however, this article was not a drug the name of which was recognized in the National Formulary.

LIBELED: 10–2–61, N. Dist. Ga.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the declaration of the quantity of belladonna alkaloids (hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide) was false and misleading as applied to a product containing less than the declared amount of belladonna alkaloids, and the label declaration "NF" on some bottles, representing that the article was a drug, the name of which was recognized in the National Formulary, an official compendium, was false and misleading; 502(d)—the article in some bottles contained phenobarbital, a derivative of barbituric acid, and its label failed to bear the statement "Warning–May be habit forming"; 502(f)(1)—the labeling failed to bear adequate directions for use in that it was in dosage form in which it may be dispensed, and the label did not bear the common or usual dosage; and 503(b)(4)—the article in some bottles was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–1–61. Consent—claimed by Cambridge Pharmaceuticals and released under bond for reprocessing.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE*

6865. Various prescription drugs. (F.D.C. No. 46639. S. Nos. 13–148/55 T.)

QUANTITY: Approximately 300 boxes, btls., vials, etc., at Chicago, Ill., in possession of Jack's Drugs.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample," "Physician's Professional Package," "Professional Sample Not To Be Sold," "Professional Sample," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer, Jack's Drugs, from physicians' samples into bottles to which had been affixed labels bearing the brand names of the drugs, a "complimentary–not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois; some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing a "complimentary–not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois; some of the articles had been on the premises when the drug store had been purchased by the dealer; and some of the articles had been obtained by the dealer from a local physician.

LIBELED: 11–13–61, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample Not To Be Sold," "Physician's Sample," "Sample–Not To Be Sold," "Physician's Professional Package," "Professional Sample Not To Be Sold," "Professional Sample," and similar wording on the labels of the articles, were false and misleading as applied to the articles in the possession of a repacker and intended for sale, and not intended for use as "complimentary–not for sale"

*See also Nos. 6861, 6863, 6864.

samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of the repacked articles failed to bear adequate directions for use and the articles were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug, as required by regulations.

DISPOSITION: 12–14–61. Default—destruction.

6866. Various prescription drugs. (F.D.C. No. 46583. S. Nos. 75/85 T.)

QUANTITY: 8,355 tablets and capsules and 204 containers of salves and liquids, and 1 227-tablet btl. labeled *Miluretic*, at Macclenny, Fla., in possession of Paul's Drug Store.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "Physician's Sample," "Sample: Not To Be Sold," "Clinical Trial Supply," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles which had not been repacked by the dealer consisted of quantities of prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing the words "Clinical Trial Supply," or similar wording, and the names of the manufacturers, packers, or distributors located outside the State of Florida. Some of the articles consisted of quantities of prescription drugs which had been repacked from physicians' samples into containers which had labels bearing the brand names of the drugs, a "complimentary–not for sale" professional sample legend, and the names of manufacturers, packers, or distributors located outside the State of Florida.

LIBELED: 10–23–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Physician's Sample," "Sample: Not To Be Sold," "Clinical Trial Supply," and similar wording on the labels of some of the articles, were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drugs, as required by regulations; 501(d)(2)—tablets which were not *Miluretic tablets* had been substituted in part for *Miluretic tablets* in the 227-tablet btl. labeled "Miluretic"; and 502(a)—the name "Miluretic" on the label of one 227-tablet btl. was false and misleading in that such name represented that the article consisted entirely of *Miluretic tablets*, whereas the article did not consist entirely of such tablets but did consist in part of other tablets.

DISPOSITION: 11–27–61. Default—destruction.

6867. Livesay's drug products. (F.D.C. No. 45933. S. Nos. 5–731/9 R, 79–341/8 R.)

QUANTITY: 9 cases, 12 16-oz. btls. each, of *laxative syrup;* 20 cases, 12 8-oz. btls. each, of *Formula No. 10;* 13 cases, 24 16-oz. btls. each, of *S & L Compound No. 25;* 4 cases, 12 4-oz. btls. each, of *antacid powder;* 101 cases, 12 8-oz. btls. each, of *diuretic and alkaline;* 20 cases, 6 16-oz. btls. each, of *Formula No. 150;* 13 cases, 12 16-oz. btls. each, of *Formula No. 161;* and 17 cases, 12 16-oz. btls. each, of *Alfatea;* at Pennington Gap, Va., in possession of Walter B. Livesay, t/a W. B. Livesay Products Co.

SHIPPED: Between 9–9–59 and 3–8–61, from outside the State of Virginia.

LABEL IN PART: (Btls.) "Livesay's Laxative Syrup," "Livesay's Formula No. 10 Bitter Tonic and Stomachic," "Livesay's S & L Compound Number 25," "W. B. Livesay's Antacid Powder," "Livesay's Diuretic & Alkaline," "Livesay's Formula No. 150 Stomachic," "Livesay's Formula No. 161 Analgesic," "Livesay's Alfatea Elixir with Sodium Salicylate and Iron."

LIBELED: 6–6–61, W. Dist. Va.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*laxative syrup*) for the treatment of gallbladder trouble; (*Formula No. 10*) for the treatment of hepatitis, jaundice, and infection of the liver; (*S & L Compound Number 25*) for the treatment of liver troubles and gallstones; (*antacid powder*) for the treatment of bleeding ulcers of the stomach; (*diuretic and alkaline*) for the treatment of bladder trouble, pus in urine, and Bright's disease; (*Formula No. 150*) for the treatment of prostate gland trouble; (*Formula No. 161* and *Alfatea*) for the treatment of inflammatory rheumatism; which were the diseases, conditions, and purposes for which the articles were recommended in oral statements made by the dealer.

DISPOSITION: 8–10–61. Walter B. Livesay, claimant, having consented to the condemnation of the articles and to the entry of an injunction, a decree was entered condemning the articles and releasing them under bond to be brought into compliance with the law, and permanently enjoining the claimant against the doing of any act with respect to the above-mentioned articles or any similar articles, while held for sale after shipment in interstate commerce, which would result in such articles being accompanied by any written, printed, or graphic matter representing that the articles are adequate and effective for the diseases mentioned above or any other disease or condition of man. The claimant was further enjoined from holding for sale these or any similar articles which fail to bear in their labeling (1) all of the conditions, purposes, and uses for which such articles are intended to be used and for which they are represented, by any means, to the public; and (2) sufficient information to enable the layman to use the articles for such purposes safely, intelligently, and efficaciously.

6868. Livesay's drug products. (F.D.C. No. 46033. S. Nos. 5–728/30 R.)

QUANTITY: 16 cases, 6 16-oz. btls. each, of *Livesay's Stomachic and Alterative;* 24 cases, 12 16-oz. btls. each, of *Livesay's Formula B–W Tonic and Sedative;* and 30 cases, 12 16-oz. btls. each, of *Formula No. 99*, at Pennington Gap, Va.

SHIPPED: Between 8–27–59 and 3–24–61, from Greenville, S.C., by Table Rock Laboratories, Inc. (Libby, Edwards & Brown, Inc.).

LABEL IN PART: (Btl.) "Livesay's Stomachic and Alterative Each fluid ounce contains the extractives from: Prickley Ash Berries, Bay Berry Bark of Root, Sumac Berries, Black Ash Bark, Cayenne Pepper * * * Prepared For: W. B. Livesay Products Corporation, 1111 Joslyn, Pennington Gap, Va."; "Livesay's Formula B–W Tonic and Sedative Useful in diminishing the frequency of pulse, quieting irritation and allaying cough. Also valuable in hemorrhages, diarrhea and dysentery. Active ingredient: Bugle Weed Directions: * * * Caution: * * * Prepared for W. B. Livesay Products Co. Pennington Gap, Virginia"; and "Formula No. 99 Liquid Stomachic and Tonic Made From Natural Herbs * * * Contains: Extractions from Wild Cherry, White Poplar, Black Willow, and Red Dog Wood Barks, Wild Ginger, Barberry Root, Spignet, Calamus, Goldenseal, Sarsaparilla and Sassafras Root, Wintergreen. Directions * * * Prepared For W. B. Livesay Products Company, Pennington Gap, Va."

LIBELED: 6–24–61, W. Dist. Va.

CHARGE: *Livesay's Stomachic and Alterative*, 502(a)—when shipped, the label statements "Stomachic and Alterative" were false and misleading, since they implied that the article had therapeutic value which it did not have; and 502(f)(1)—the labeling of the article failed to state the specific conditions for which the article was intended to be used.

Formula No. 99, 502(a)—when shipped, the label statements "Stomachic and Tonic" were false and misleading, since they implied that the article had therapeutic value which it did not have; and 502(f)(1)—the labeling of the article failed to state the specific conditions for which the article was intended to be used.

Livesay's Formula B–W Tonic and Sedative, 502(a)—when shipped, the label statement "Tonic and Sedative," and other statements on the label, represented and suggested that the article was adequate and effective as a treatment for diminishing the pulse, quieting irritation, allaying coughing, hemorrhages, diarrhea, and dysentery, which statements were false and misleading, since the article was not a tonic or sedative, and was not adequate and effective as a treatment for such conditions or for such purposes.

DISPOSITION: 1–5–62. Default—destruction.

6869. Flu Caps capsules. (F.D.C. No. 46030. S. No. 17–132 R.)

QUANTITY: 1 drum, containing 25,000 capsules, and 77 display ctns., each ctn. containing 12 btls. of 12 capsules each, at Indianapolis, Ind., in possession of Briggs Laboratory.

SHIPPED: 10–27–60, from Baudette, Minn.

LABEL IN PART: (Drum) "Special formula capsules * * * Each capsule contains not less than: Strontium Salicylate (4 gr.) 256 mg. Aspirin (4 gr.) 256 mg. Phenacetin (2.5 grs.) 150 mg. Caffeine (¼ gr.) 16 mg. Capsicum Powder (¼ gr.) 16 mg. * * * Briggs Laboratory, 2428 Broadway Indianapolis, Indiana"; (btl.) "FLUCAPS * * * Briggs' Special Formula * * * Briggs' Lab. Products Co. * * * Active Ingredients"; and (display ctn.) "Flu Caps Special Formula * * * Briggs Laboratory Products Co. Indianapolis."

RESULTS OF INVESTIGATION: The article in the display cartons was repacked and labeled by the dealer from bulk stock shipped as described above. The dealer also had on hand a number of empty display cartons and empty bottles.

LIBELED: On or about 7–11–61, S. Dist. Ind.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relief of flu, colds, chills, rheumatism, grippe, and associated conditions; and 502(f)(2)—the labeling of the article failed to bear the warning statement "Keep out of reach of children."

DISPOSITION: 10–20–61. Default—destruction.

6870. Cobasal tablets and Cobaden injection. (F.D.C. No. 46588. S. Nos. 97–902 R, 97–904 R.

QUANTITY: 21 cases, 12 100-tablet btls. each, and 10 1,000-tablet btls. of *Cobasal;* and 48 vials of *Cobaden injection,* at Rensselaer, N.Y., in possession of Rand Pharmaceutical Co., Inc.

SHIPPED: (*Cobasal tablets*) 2–1–61, from Worcester, Mass.; (*Cobaden injection*) 4–24–61, from Decatur, Ill.

LABEL IN PART: (Btl.) "Cobasal * * * Each 2 Tablets contains: Dipyrone 0.125 Gm Para-amino-benzoic Acid 8 gr. Salicylamide 6 gr. Vitamin B–12 Activity 5 mcg. Distributed by Rand Pharmaceutical Company, Inc., Rensselaer, N.Y. Caution: * * * Dosage: 2 tablets." and (vial and ctn.) "10 cc. No. 125 Multiple Dose Sterile Vial Cobaden * * * Caution * * * Manufactured for Rand Pharmaceutical Co., Inc., Rensselaer, N.Y. Each 1 cc. contains: Adenosine-5-Monophosphoric Acid 25 mg. (present as Sodium Salt) Vitamin B–12 (Crystalline) 60 mcg. * * * Intramuscular."

ACCOMPANYING LABELING: Leaflets entitled "Cobaden Adenosine-5-monophosphoric acid plus Vitamin B_{12}," "Adenosine with Vitamin B_{12}" and "Cobasal (Rand) A new Anti-Rheumatic * * * Alone or in conjunction with * * * Cobaden."

LIBELED: 10–27–61, N. Dist. N.Y.

CHARGE: 502(a)—while held for sale, (*Cobasal tablets*) the labeling contained false and misleading representations that the article was adequate and effective for the treatment of neuritis; pruritus; pruritus due to penicillin sensitivity; chronic venous insufficiency; renal and gall-bladder colics; pneumonia; meningeal inflammations; cholelithiasis; iritis; and herpes; and to promote growth and body development; and the labeling also contained false and misleading representations that there were no contraindications for use of the article; and (*Cobaden injection*) the labeling contained false and misleading representations that the article was adequate and effective for the treatment of bursitis; osteoarthritis; pruritus ani, vulvae, and scroti; pruritus associated with penicillin reaction; and chronic venous insufficiency; and 502(f)(1)—(*Cobasal tablets*) the labeling failed to bear adequate directions for use, since its labeling failed to bear adequate information for use of the drug, including relevant hazards, contraindications, side effects, and precautions under which practioners licensed by law to administer the drug, could use it safely and for the purposes for which it was intended.

DISPOSITION: 1–4–62. Default—destruction.

6871. Devine's remedies. (F.D.C. No. 46474. S. Nos. 6–282/5 T.)

QUANTITY: 144 10-oz. pkgs. of *10/2 Corn and Callous Reducer;* 864 5- or 3- or 1-fluid oz. tubes of *Kool-Foot Powder;* 576 3¾-oz boxes of *Per-Fo Footbath;* and 720 envelopes of *Karbo-Silekon Corn Reducer,* at Boston, Mass., in possession of Darryl Jensen.

SHIPPED: 8–9–61, from Chicago, Ill., by Devine's Remedies, Inc.

LABEL IN PART: (Pkg.) "Devine's New 10/2 Free 'Karbo-Silekon' Eraser Enclosed"; (tube) "Devine's Kool-Foot"; (box) "Improved Devine's Per-Fo * * * Devine's Per-Fo a foot and body bath"; and (envelope) "Devine's Karbo-Silekon Corn & Callus Reducer."

ACCOMPANYING LABELING: Promotional material reading in part "Feet Hurt Burn Tired Itch Ache? Then Use Devine's Kool Foot * * * Pain Sufferers * * * Use Devine's Zina-Ray Oil."

LIBELED: 9–29–61, Dist. Mass.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective (*10/2 Corn and Callous Reducer*) for the prevention of athlete's foot, reducing corns, and preventing corns and calluses; (*Kool-Foot Powder*) for overcoming athlete's foot, relieving sunburn, bruises, external cuts, and stiffness and soreness of joints; and (*Karbo-Silekon Corn Reducer*) for reducing corns and calluses; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes for which the articles were intended, namely, as a treatment for (*10/2 Corn and Callous Reducer*) relieving in four days time, corns, calluses, fungus of the feet and athlete's foot; (*Kool-Foot Powder*) relieving in one minute, inflamed or aching feet, any kind of rash, sunburn, bunions, and athlete's foot; (*Per-Fo Footbath*) cleansing and purifying the inside of the feet, making one feel that they have "new feet," flushing out all the impurities in the feet; and (*Karbo-Silekon Corn Reducer*) removing corns completely, which were the conditions and purposes for which the articles were offered, in oral statements made by Darryl Jensen, salesman for Devine's Remedies, Inc.

DISPOSITION: 11–27–61. Default—destruction.

6872. Kneipp herb teas. (F.D.C. No. 46578. S. Nos. 39–708/20 T, 39–828/32 T, 39–834/40 T, 41–801/2 T.)

QUANTITY: 98 cases of 165 dozen pkgs., 6 cases of 377 cans, and 9 cases of 327 cans at New York, N.Y., in possession of Alfred L. Ettlinger, Inc.

SHIPPED: On various dates between 1960 and 1961, from Wurzburg, Germany.

LABEL IN PART: (Pkg.) "Kneipp Carminative Herb Tea Contents: ca. 3 oz."; (cans) "Kneipp Carminative Instant Tea * * * Contents: ca. 120 g."

ACCOMPANYING LABELING: Leaflet entitled "Imported Kneipp Herb Teas Kneipp Pressan (Instant) Teas."

RESULTS OF INVESTIGATION: Each package and each can bore a number corresponding to a number in the leaflet which indicated on the leaflet the condition for which the tea was to be used. The dealer had copies of the leaflet printed locally.

LIBELED: 10–17–61, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of some of the articles contained false and misleading representations that the articles were adequate and effective for the treatment of diseases of the nerves, diseases of the kidneys and bladder, rheumatism, insomnia, for reducing body weight, to promote the health of the family, colds and flu, diseases of the gallbladder and liver, to purify the blood, diseases of the arteries, asthma, to promote the appetite, hemorrhoids, to control the uric acid in the body, diseases of the heart and circulatory system, cough, to control silicic acid in the body, and diseases of the stomach; and the label statement of some of the articles "Carminative

Herb Tea" was false and misleading since the intended use of the articles was not as a carminative, but as a laxative and as a diuretic; and 502(f)(1)—the labeling of all of the articles failed to bear adequate directions for the intended use of the articles as indicated in the leaflet.

DISPOSITION: 11–2–61. Consent—claimed by Alfred L. Ettlinger, Inc., and relabeled.

6873. Chloraseptic mouthwash. (F.D.C. No. 45701. S. Nos. 4–718 R, 5–582 R.)

QUANTITY: 30 ctns., 24 8-oz. btls. each, and 9 ctns., 24 6-oz. btls. each, at Washington, D.C.

SHIPPED: Between 1–31–61 and 3–13–61, from Riverdale, Md., by Chloraseptic Co.

LABEL IN PART: (Ctn.) "With Sprayer Chloraseptic Mouthwash And Gargle Anesthetic Antiseptic Alkaline * * * Active Ingredients: Sodium Phenolate, Menthol, Thymol, Sodium Tetraborate, Phenol (1.4%), Glycerin and Chlorophyll. Directions: * * * The Chloraseptic Company, Washington 1, D.C."

ACCOMPANYING LABELING: Folders reading in part, "Medical Annals of the District of Columbia * * * Comparative Study Chloraseptic" and "Bactericidal–Fungicidal–Anesthetic * * * Chloraseptic"; leaflets reading in part, "Note: This listing appears in the 'Professional Products Information' section," "Chloraseptic Mouthwash * * * A new approach in the Treatment of Sore Throats (And Baby Teething) For Children," and "Professional Prices and Samples."

LIBELED: 4–4–61, Dist. Columbia; amended libel 5–18–61.

CHARGE: 502(a)—when shipped and while held for sale, the bottle and carton label, and the labeling accompanying the article, contained false and misleading representations that the article was an adequate and effective treatment for sore gums, soreness of mouth and throat tissues, infections of the mouth and throat (including infections due to various strains of streptococci, staphylococci, and other organisms which cause deep throat infections), pharyngitis, acute tonsilitis, pericoronitis, Vincent's infection, aphthous ulcers, and herpetic lesions; that the article is significantly more effective than injectable pencillin in the treatment of pharyngeal streptococcal infections; and that use of the article will destroy all bacteria in the oral cavity; and 502(f)(2)—the labeling failed to warn that if fever was present or the condition for which the article was used persisted, its use should be discontinued and a physician consulted.

DISPOSITION: 11–16–61. Default—destruction.

DRUGS FOR VETERINARY USE

6874. Veterinary drugs. (F.D.C. No. 46569. S. Nos. 66–173/4 R.)

QUANTITY: 698 1-lb. and 7 1-lb. cans of *piperazine wormer*; 2 cases, 25 1-lb. bags each, and 5 cases, 15 1-lb. cans each, of *sulfathiazole sodium*, at Springdale, Ark., in possession of Lu Mar Laboratories.

SHIPPED: Between 9–30–60 and 7–27–61, from Valley Stream, N.Y., and Kansas City, Mo.

LABEL IN PART: (Bag) "Piperazine Citrate–36% Net Weight–1 pound Use at 1 lb. per 35 gallons of water"; (can) "Lu Mar Piperazine Wormer Net Contents One Pound * * * Active Ingredients: Piperazine Citrate 36% * * * Man-

ufactured For Lu Mar Laboratories, Springdale Arkansas"; (bag) "1 lb." (hand written); (can) "Lu Mar One Pound Sulfathiazole Sodium * * * Manufactured for Lu Mar Laboratories Springdale, Arkansas."

RESULTS OF INVESTIGATION: All lots of the articles were repacked and labeled by the dealer.

LIBELED: 10–9–61, W. Dist. Ark.

CHARGE: 502(a)—while held for sale, the labeling, namely, the repack labels, contained false and misleading representations that the article (*piperazine wormer*) was adequate and effective for the removal of large roundworms (*Ascaridia*) from chickens and turkeys; and of large roundworms (*Ascaris*) and nodular worms (*Oesophagostomum*) from hogs; (*sulfathiazole sodium*) was adequate and effective for the treatment of all staphylococcal infections in cattle, swine, horses, mules, sheep, goats, and poultry; 502(b)(1)—the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—(*sulfathiazole sodium*) the label failed to bear the common or usual name of the drug; and 502(f)(1)—(*piperazine wormer* and *sulfathiazole sodium*) the labeling failed to bear adequate directions for use.

DISPOSITION: On 11–17–61, Luther Martin, claimant, filed an answer denying that the articles were misbranded. On 1–4–62, the claimant having consented, the court entered a decree of condemnation and the articles were relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

6875. Imitation Hydrodiuril tablets. (F.D.C. No. 46455. S. No. 69–581 R.)

QUANTITY: 1 bottle of 550 tablets at Chicago, Ill., in possession of Lazar Drugs, Inc.

SHIPPED: Prior to 2–28–61, from outside the State of Illinois.

LIBELED: 9–18–61, N. Dist. Ill.

CHARGE: 501(d)(2)—while held for sale, a substance other than *Hydrodiuril tablets* was substituted for *Hydrodiuril tablets*; 502(i)(2) and (3)—the article was an imitation of another drug, and was offered for sale under the name of another drug; and 502(a)—the label designation "MSD Tablets Hydrodiuril * * * 50 mg. Merck Sharp & Dohme" was false and misleading as applied to an article which was not 50 mg. tablets of *Hydrodiuril* manufactured by Merck Sharp & Dohme.

DISPOSITION: 10–19–61. Default—destruction.

6876. Insta-Pep tablets. (F.D.C. No. 46765. S. No. 13–789 T.)

QUANTITY: 13 cases, 6 combination pkgs. each, 1 50-tablet btl. and 1 25-tablet btl. in each pkg., at Gary, Ind.

SHIPPED: 3–8–61, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Btl. and ctn.) "Insta-Pep with Dynamol and 'Vitamin Feed' For prolonged Vitamin-Mineral Release A high potency therapeutic *Vitamin-Iron Formula* Sole Distributors: Drug Research Corp., New York, N.Y. Each Tablet Contains: * * * Cobalamin Concentrate (Vit. B_{12} Activity) 3.0 mcg. Dynamol (D.R.C. Brand of Caffeine Alkaloid Anhydrous) 3.0 gr. * * *

*See also Nos. 6864, 6866.

A Stimulant and therapeutic formula"; (comb. pkg.) "Insta-Pep A Fast-Acting Stimulant Combined With High Potency Vitamin-Iron Formula Each Tablet Releases Vitamins-Minerals Three Times a Day."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 50 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–5–61, N. Dist. Ind.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess, since the article contained less than the declared amount of vitamin B_{12}; 502(a)—the label statement "Cobalamin Concentrate (Vit. B_{12} Activity) 3.0 mcg." was false and misleading; 502(a)—when shipped, the name of the article "*Insta-Pep*" and certain statements on its label contained false and misleading representations and suggestions that the article was adequate and effective to provide instant pep, that the article was a high potency therapeutic vitamin and iron formula, and that "Dynamol" was an important active ingredient.

DISPOSITION: 1–18–62. Default—destruction.

6877. Ferrous sulfate tablets. (F.D.C. No. 46323. S. No. 97–303 R.)

QUANTITY: 1 drum containing 42,000 tablets at Buffalo, N.Y.

SHIPPED: 3–13–61, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: (drum) "Tablets Ferrous Sulfate USP 0.324 gm (5 gr.) Stock No. 1–193–300 Lot No. 8190 Cowley Pharmaceuticals, Inc., Auburn, Mass. * * * Adult dose: 1 or 2 tablets 3 times daily * * * For Iron Deficiency Anemia."

RESULTS OF INVESTIGATION: Analysis showed that the article contained ferrous sulfate in excess of amount permitted.

LIBELED: 8–29–61, W. Dist. N.Y.

CHARGE: 501(b)—when shipped, the strength of the article differed from the USP Standard for *Ferrous Sulfate Tablets;* 502(a)—the label statement "Ferrous Sulfate USP" was false and misleading as applied to the product which failed to conform to the USP Standard for *Ferrous Sulfate Tablets.*

DISPOSITION: 1–19–62. Default—destruction.

6878. Decavitamin tablets. (F.D.C. No. 46105. S. No. 7–427 R.)

QUANTITY: 41 cases, each containing 144 100-tablet btls., and 11 100-tablet btls., at Worcester, Mass.

SHIPPED: During May 1958, from Lathrop, Calif. This was a return shipment.

LABEL IN PART: "Decavitamin Tablets, USP * * * Each tablet contains: * * * Cyanocobalamin (Vit. B–12) 2 mcg."

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 75 percent of the declared amount of vitamin B_{12}.

LIBELED: 7–24–61, Dist. Mass.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Cyanocobalamin (Vit. B–12) 2 mcg." was false and misleading as applied to an article which contained less than the declared amount of vitamin B_{12}.

DISPOSITION: 11–6–61. Default—destruction.

6879. Rubber prophylactics. (F.D.C. No. 46763. S. Nos. 19-772/3 T.)

QUANTITY: 110 cartons, each containing 144 prophylactics in pkgs. of 2 each, at Dallas, Tex.

SHIPPED: 10-30-61, from Kansas City, Mo., by M&M Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics Package of Two M&M Rubber Co., K.C. 8, Mo. Sold For The Prevention of Disease Only." and (pkg.) "Tops Prophylactics Package of Two * * * M&M Rubber Co., Kansas City 8, Mo."

RESULTS OF INVESTIGATION: Examination showed that 3, or 2.0 percent of 149 prophylactics (Spartans), and 4, or 1.78 percent of 224 prophylactics (Tops), were defective in that they contained holes.

LIBELED: Between 11-29-61 and 1-18-62, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements (Spartans) "Sold For The Prevention of Disease Only" and (Tops) "Prophylactics" were false and misleading as applied to articles containing holes.

DISPOSITION: 1-18-62. Default—destruction.

6880. Rubber prophylactics. (F.D.C. No. 46167. S. No. 47-621 R.)

QUANTITY: 4 cases, 50-gross ctns. each, containing boxes of 3 units, at Detroit, Mich.

SHIPPED: 4-20-61, from Akron, Ohio, by March Rubber & Plastics Co.

LABEL IN PART: (Box) "Checks Deluxe Thin Prophylactics Package of Three Sold and Intended For Prevention of Disease Only March Rubber and Plastics Co., Inc., Akron, Ohio."

RESULTS OF INVESTIGATION: Examination of 190 prophylactics showed that 1.6 percent contained holes.

LIBELED: On or about 8-14-61, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Sold and Intended For Prevention of Disease Only" was false and misleading as applied to articles containing holes.

DISPOSITION: 9-20-61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6881. Pile-Aids tablets. (F.D.C. No. 43211. S. No. 9-790 P.)

INFORMATION FILED: 7-22-59, W. Dist. Pa., against Nutrition Square, Inc., t/a Pile-Aids Co., Pittsburgh, Pa.

SHIPPED: 9-1-58, from Pennsylvania to Ohio.

LABEL IN PART: (Btl.) "Pile-Aids Tablet * * * This exclusive imported herbal compound contains: Cyclamen Europaeum Elecampane (Inula Heleniom) Sulphur Distributed by Pile-Aids Company Pittsburgh 12, Pa."

ACCOMPANYING LABELING: Circular entitled "Instructions for Taking Pile-Aids Tablets" and a circular entitled "Information for Pile Sufferers."

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*See also Nos. 6861, 6863-6866, 6868-6873, 6875-6880.

CHARGE: 502(a)—when shipped, the name of the article "*Pile-Aids*" and the statements in the labeling which represented and suggested that the article was adequate and effective for the treatment of piles were false and misleading since the article was not adequate and effective for such treatment.

PLEA: Guilty.

DISPOSITION: 10–9–61. $200 fine, plus costs.

6882. **Mineralized cookies.** (F.D.C. No. 45781. S. Nos. 68–595/6 R.)

QUANTITY: 42 ctns., 12 pkgs. each, at Tulsa, Okla.

SHIPPED: Between 12–22–60 and 3–3–61, from Alhambra, Calif., by El Molino Mills.

LABEL IN PART: (Display case) "El Molino Kitchens * * * Best . . . from the Land!"; (pkg. sticker label) "El Molino Kitchens Mineralized Cookies"; (cardboard in bottom of pkg.) "In each 3 cookies the added Minerals and Trace Elements supply the following."

ACCOMPANYING LABELING: Leaflets entitled "The Story Of . . . El Molino Kitchens Mineralized Cookies."

LIBELED: 5–8–61, N. Dist. Okla.; amended libel 7–25–61, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of borderline conditions with indefinite symptoms, instability of the nervous system, lack of energy, lowered resistance to disease, aches and pains, and for regaining and maintaining health, for vigor and proper growth, and for repair of tissues.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 6–8–61, the case was transferred to the Northern District of California. On 11–3–61, a default decree of condemnation was entered and the article destroyed.

6883. **Safflor capsules.** (F.D.C. No. 46462. S. No. 68–824 R.)

QUANTITY: 57 100-capsule btls. at Milwaukee, Wis., in possession of Haug Drug Co.

SHIPPED: 5–25–61, from Detroit, Mich.

LABEL IN PART: (Btl.) "Haug's Safflor Capsules Haug's Safflower Oil Each Capsule Contains * * * As a Dietary Supplement, * * * Distributed by Haug Drug Company, Milwaukee 9, Wis."

ACCOMPANYING LABELING: Booklets entitled "Haug's Price List and Therapeutic Guide"; cards entitled "Safflor Capsules–For Reducing Serum Cholesterol File Card No. 558"; leaflets entitled "Excerpts from the Symposium on fats in human nutrition" and "What's all the Talk About Serum Cholesterol Levels and Atherosclerosis?"; and additional bottle labels.

RESULTS OF INVESTIGATION: The article was shipped in bulk and repacked and labeled by the dealer.

The accompanying labeling was printed locally for the dealer and was used in promoting sales of the article.

LIBELED: 9–20–61, E. Dist. Wis.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to control the cholesterol level of the blood, and for the treatment and prevention of heart disease and atherosclerosis.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–10–61. Default—destruction.

6884. **Rexall Super Plenamins.** (F.D.C. No. 44863. S. Nos. 43–373/5 R.)

QUANTITY: 137 cases, 12 8-oz. ctnd. btls. each, of *Super Plenamins Junior Liquid Vitamins;* 27 cases, 144 36-tablet btls. each, 108 cases, 36 72-tablet btls. each, 19 cases, 24 288-tablet btls. each, and 169 cases, 36 144-tablet btls. each, of *Super Plenamins Multi Vitamins with Minerals;* and 6 cases, 144 36-tablet btls. each, 7 cases, 144 72-tablet btls. each, and 9 cases, 72 144-tablet btls. each, of *Super Plenamins Junior*, at Portland, Oreg.

SHIPPED: Between 10–13–59 and 8–24–60, from St. Louis, Mo., by Rexall Drug Laboratory.

LABEL IN PART: (Btl.) "For Children 1 to 12 years * * * Rexall Super Plenamins Junior Liquid Vitamins 10 Vitamins with Red Vitamins B_{12} plus L-lysine * * * Rexall Drug Company"; (ctn.) "Rexall Super Plenamins Junior * * * Provide generous amounts of all the vitamins children are known to need for health growth (contains L-lysine, a growth-aid cereal diets lack.) * * * Rexall Drug Company"; (btl. and ctn.) "Rexall Super Plenamins Multi Vitamins with Minerals 11 Vitamins and 12 Minerals with B_{12}, Iron plus Liver Concentrate * * * Rexall Drug Company" and "Rexall Super Plenamins Junior 11 Vitamins with B_{12} plus Iron and Liver Rexall Drug Company."

ACCOMPANYING LABELING: Leaflets entitled "Who Wouldn't Pay A Nickel A Day?" "Free 18 Day Supply Super Plenamins," and "Know Who Makes the Vitamins you BUY?" used in promoting sales of "Super Plenamins Multi Vitamins with Minerals."

LIBELED: 8–25–60, Dist. Oreg.; amended libel 1–26–61.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of (*Super Plenamins Junior Liquid Vitamins*) nervous irritability, constipation, indigestion, and loss of energy in children; that the presence of these conditions indicates that there is an increased need for the vitamins, iodine, and L-lysine in the article; and that the vitamins and L-lysine in the article would promote healthy growth in children; (*Super Plenamins Multi Vitamins with Minerals*) lack of appetite, loss of energy, nervous irritability, insomnia, constipation, indigestion, rundown condition, listlessness, and lack of "get up and go"; that the article would stimulate red blood cell formation because it contained the combination of red vitamin B_{12}, folic acid, vitamin C, liver concentrate, and iron; and that use of the article would result in feeling one's best every day, enjoyment of life to the fullest, and getting the most out of life; and (*Super Plenamins Junior tablets*) lack of appetite, loss of energy, listlessness, nervous irritability, insomnia, constipation, indigestion, and rundown condition in growing children; that the presence of these conditions indicates that there is an increased need for the vitamins in the article; and that the article would stimulate red

blood cell formation because it contained the combination of red vitamin B_{12}, folic acid, vitamin C, liver concentrate and iron.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 6–8–61. The Rexall Drug & Chemical Co., claimant, having consented to the entry of a decree which declared the articles to be misbranded under 403(j) as alleged in the libel, and the court having found the articles to be misbranded under 403(j) without an adjudication of the other charges of misbranding, judgment of condemnation was entered and the articles were released under bond for relabeling.

6885. Rexall Bislumina Acid Guard tablets. (F.D.C. No. 45523. S. Nos. 26–379/80 R, 27–161 R, 27–169 R.)

QUANTITY: 124 cases, each containing a number of ctns., containing 1 50-tablet btl. and 1 6-tablet vial each, at Los Angeles and Vernon, Calif.

SHIPPED: Between 10–14–60 and 3–20–61, from St. Louis, Mo., by Rexall Drug Co.

LABEL IN PART: (Cases, ctns., btls., and insert label in vials) "Rexall Bislumina Acid Guard for relief from gastric hyperacidity contains bismuth aluminate * * * Rexall Drug Company * * * Los Angeles–St. Louis–Toronto * * * Each tablet contains: Magnesium Carbonate 400 mg; Calcium Carbonate (Chalk) 200 mg; Bismuth Aluminate 150 mg; Cortext Frangula (Buckthorn Bark) 25 mg; Calamus Root 25 mg; Carboxymethylcellulose Sodium, Peppermint Oil."

ACCOMPANYING LABELING: Leaflets entitled "Rexall Bislumina Acid Guard An amazing new tablet formulation brings prompt relief to both groups of your patients. For Physician's Information Only."

LIBELED: 3–23–61, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article, namely, the leaflets accompanying the article, contained false and misleading representations that the article was an adequate and effective treatment for peptic ulcers.

DISPOSITION: 5–2–61. Consent—claimed by Rexall Drug & Chemical Co. and leaflets destroyed.

6886. Cobalamed 1000 injection. (F.D.C. No. 46066. S. No. 2–908 R.)

QUANTITY: 300 10-cc.vials, individually ctnd., at Decatur, Ga.

SHIPPED: 6–26–61, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: (Vial) "Multiple Dose Vial Cobalamed 1000 * * * Injection Cyanocobalamin U.S.P. XVI * * * 106416 Manufactured for Medics Pharmaceutical * * * Atlanta (Decatur), Ga."

ACCOMPANYING LABELING: Insert leaflets entitled "Vitamin B_{12} Description."

LIBELED: 7–5–61, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for trigeminal neuralgia; toxic, diabetic, alcoholic, and nutritional neuritic disorders; bursitis; acute and chronic liver disease; viral hepatitis; dermatoses such as seborrheic dermatitis, psoriasis, lupus erythematosus, and topical dermatitis.

DISPOSITION: 11–1–61. Consent—claimed by Medical Chemicals Corp., and relabeled.

6887. Calorie Control food concentrate. (F.D.C. No. 46071. S. No. 47–935 R.)

QUANTITY: 256 cases, containing 12 ctns. of 4 packets each; 68 cases, 120 packets each; 16 cases, containing 36 ctns. of 4 packets each; 1 case, containing 10 ctns. of 4 packets each; 250 ctns., 40 packets each; 28 ctns., 20 packets each; 402 ctns., 4 packets each; and 251 packets, at Detroit, Mich.

SHIPPED: 9–22–61 and 11–21–61, from Evanston, Ill., by Corel Distributors.

LABEL IN PART: (Ctn.) "The J. L. Hudson Company deluxe pre-measured Calorie Control food concentrate Four packets provide vitamins, protein, minerals, and 900 calories for dietary weight control 8 ozs. Net Wt. * * * 5 appetizing delicious flavors–Chocolate, Coffee, Butterscotch, Plain, and Root Beer * * * Ingredients:" and (packet) "* * * deluxe pre-measured Calorie Control food concentrate * * * Each Packet–Net Wt. 2 Ozs. * * * Each four packets of Chocolate flavor contain 70 gm. (30.8%) of protein. Each four packets of Butterscotch, Coffee, Plain, and Root Beer flavors contain 75 gm. (31.99%) of protein. The J. L. Hudson Company, Detroit, Michigan, Distributors."

ACCOMPANYING LABELING: Leaflets reading in part "* * * deluxe pre-measured Calorie Control food concentrate."

LIBELED: 7–14–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective to prevent various ills; restore zest and vigor to people who complain of chronic fatigue; to act as a "spark plug of energy"; promote growth of children; prevent weak, tired, irritable, and cranky conditions; promote health; protect tissues from starvation; speed up the weight reducing process; prevent being weakened physically while reducing; maintain human energies at a high level; and cause the consumer to feel, look, and act years younger.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10–24–61. Consent—claimed by J. L. Hudson Co. and released under bond for removal of the leaflets from the cartons.

6888. Coffee reducing diet. (F.D.C. No. 45748. S. No. 67–335 R.)

QUANTITY: 26 cases, 12 individually ctnd. 7½-oz. jars each, and 57 individual jars, at Dallas, Tex.

SHIPPED: 2–15–61 and 3–20–61, from Chicago, Ill., by Fleetwood Co.

LABEL IN PART: (Jar) "Net Weight 7½ Oz. * * * Larson's C.R.D. A Bulking Dietary Food Supplement For use With Coffee Reducing Diet Each Ounce (4 Heaping Teaspoons) Contains: * * * Gelatin–Sucrose–Saccharin 110 Calories 13 Grams Protein–14 Grams Sucrose Distributed by Fleetwood Company–Chicago–Toronto."

ACCOMPANYING LABELING: Leaflet entitled "The Coffee Reducing Diet."

LIBELED: 5–9–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for reducing, for maintaining slimness, and as a treatment for and preventive of "all-gone feeling."

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 6–9–61, Fleetwood Co., claimant, filed an answer denying that the article was misbranded. On 9–25–61, the claimant having consented, a decree was entered condemning the article and ordering its destruction. The article was subsequently destroyed.

6889. **Bicarbonate of soda.** (F.D.C. No. 45496. S. No. 99–561 R.)

QUANTITY: 11 100-lb. bags and 24 cases, 24 1-lb. pkgs. each, at Bangor, Maine, in possession of Byron H. Smith Co., Inc.

SHIPPED: 11–2–60 and 11–22–60, from Barberton, Ohio and Peabody, Mass.

LABEL IN PART: (Pkg.) "Baking Soda Three Crow Soda Packed by The Atlantic Spice Co. Bangor, Maine."

RESULTS OF INVESTIGATION: The article in the packages was repacked and labeled by the dealer from the bulk stock shipped as described above. The dealer also had a number of empty retail packages on hand.

LIBELED: 3–3–61, Dist. Maine.

CHARGE: 502(a)—while held for sale, the label of the article contained false and misleading representations that it was an adequate and effective treatment for "sick" headache, eczema, colds, and for preserving enamel of the teeth.

DISPOSITION: 6–30–61. Consent—claimed by Byron H. Smith Co., Inc., and relabeled.

6890. **Various prescription drugs.** (F.D.C. No. 46235. S. Nos. 98–301/10 R.)

QUANTITY: 1,964 tablets and capsules and 38 other vials, bottles, or tubes, at Kansas City, Mo., in possession of Summit Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's sample," "Complimentary package," "Professional Sample," "Professional Sample–Not to be sold," and "Professional Trial Package."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians samples into containers having labels bearing the brand name of the drugs, the "complimentary–professional sample" legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Missouri; and of quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample package bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Missouri.

LIBELED: 8–4–61, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the sample legend appearing on the labels affixed to the articles was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 10–6–61. Default—destruction.

6891. **Various prescription drugs.** (F.D.C. No. 46251. S. Nos. 76–441/6 R, 76–457/60 R.)

QUANTITY: 5,069 tablets, 205 capsules, and 100 other vials and btls., at Charlotte, N.C., in possession of Sterling Drug Store, Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "For Clinical Use," "Physician's Sample," and "Sample Not To Be Sold."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by Sterling Drug Store, Inc., from physicians samples into containers having labels bearing the brand name of the drugs, the "complimentary–professional sample" legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of North Carolina; and of quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of North Carolina.

LIBELED: 8–16–61, W. Dist. N. C.

CHARGE: 502(a)—while held for sale, the sample legend appearing on the labels affixed to the articles was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not to be sold" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 10–19–61. Default—destruction.

6892. Various prescription drugs. (F.D.C. No. 46108. S. Nos. 97–746/50 R.)

QUANTITY: 7 boxes, 2 4-capsule btls. each, of Terramycin; 91 boxes, 2 4-capsule btls. each, of Cosa-Tetracyn; and 34 folders, each containing 14 tablets of Daricon, at Erie, Pa., in possession of Eckerd's Kwik-Chek, Inc., warehouse.

SHIPPED: During January or February 1960, by a salesman for Pfizer Laboratories, Clifton, N.J.

LABEL IN PART: (Btls.) "Professional Sample Terramycin Brand of Oxytetracycline 250 mg. Caution * * * Pfizer Laboratories * * * New York" and "Professional Sample Cosa-Tetracyn glucosamine potentiated tetracycline 250 mg. Pfizer Laboratories * * * New York, New York"; (folder) "Daricon Oxyphencyclimine Hydrochloride * * * Caution * * * Professional Sample * * * Pfizer Laboratories * * * Brooklyn, New York."

RESULTS OF INVESTIGATION: The articles were physicians' complimentary samples delivered to the dealer as replacements for nonreturnable drugs.

LIBELED: 8–4–61, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the statement "Professional Sample" on the labels of the articles was false and misleading as applied to those articles which were intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

DISPOSITION: 10–16–61. Default—destruction.

6893. Mirandol tablets. (F.D.C. No. 46267. S. Nos. 70–448/50 R.)

QUANTITY: 191 cases, 12 60-tablet boxes each, and 82 cases, 12 180-tablet boxes each, at Chicopee, Mass., in possession of National Health Products.

SHIPPED: 10–10–57, from Cleveland, Ohio.

LABEL IN PART: (Box) "Mirandol 35 Elements All In One Hi-Potency Tablet Multi-Vitamin Mineral Tablets 19 Vitamins Complete B–Complex 10 Minerals Plus Liver, Yeast, Chlorophyll, Wheat Germ Oil And Others * * * 180

tablets–90 day supply Distributed by National Health Products * * * Springfield, Mass."

ACCOMPANYING LABELING: Leaflet entitled "Feeling Low? Here It Is * * * Mirandol" and folder entitled "Mirandol" (printed in the Polish and English languages).

RESULTS OF INVESTIGATION: The leaflets and folders were mailed to customers by the dealer.

LIBELED: 8–21–61, Dist. Mass.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of "feeling low" conditions, sickness, rheumatism, arthritis, headache, kidney troubles, anemia, poison in the body, insomnia, and premature old age.

DISPOSITION: 11–20–61. Consent—claimed by National Health Products and accompanying labeling destroyed.

6894. Cancer treatment. (F.D.C. No. 45951. S. Nos. 58–372/3 R.)

QUANTITY: 1 ctn., containing 13 unlabeled btls. of amber-colored liquid and 13 unlabeled btls. of clear liquid, at Chicago, Ill.

SHIPPED: 5–18–61, from Hartford, Conn., by George S. Zuccala.

LABEL IN PART: (Slip in ctn.) "Amber Color Pooled Z–50 Light Acqua Color X–9 This two for good will, gift from Dr. Zuccala."

ACCOMPANYING LABELING: Leaflets entitled "A New Approach To Cancer Therapy by Pooled or Autogenous Preparation Zuccala Method–Addendum," "How To Order and Use Autogenous Anti-Cancergen Z–50," "Statement of Investigator To: Zuccala Research Laboratory, Inc.," and "The National Research Foundation, Inc. * * * The Zuccala Concept in Cancer Therapy, By Harold J. Wilson, M.D."; and reprints from the Hartford Times, Friday, Dec. 2, 1960 entitled "State Authorizes 2 Cancer Formulas."

RESULTS OF INVESTIGATION: Examination showed the article to be (*Z–50*), an amber-colored liquid, and (*X–9*), a clear liquid, purported to be a modification of gloxylide cancer treatment.

LIBELED: 6–14–61, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective as a treatment for cancer; and 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents.

DISPOSITION: On 7–31–61, William F. P. Phillips, M.D., claimant, filed an answer denying that the article was misbranded. On 11–17–61, the claimant having consented, the court entered a decree of condemnation and the article was destroyed.

6895. Coach-Aid Stim-O-Stam tablets and Coach-Aid N. B. tablets. (F.D.C. No. 46576. S. Nos. 1–726 R, 1–728/30 R.)

QUANTITY: 5 1,000-tablet cans and 35 150–tablet cans of *Coach-Aid Stim-O-Stam tablets* and 9 1,000-tablet cans and 12 500-tablet cans of *Coach-Aid N.B. tablets* at Leesburg, Fla.

SHIPPED: Between 10–15–59 and 9–9–60, (*Coach-Aid Stim-O-Stam tablets* and 9-can lot of *Coach-Aid N.B. tablets*) from Houston, Tex., by Coach-Aid, Inc.; (12-can lot of *Coach-Aid N.B. tablets*) from Hot Springs, Ark., by Health Research, Inc.

LABEL IN PART: (Cans) "Stim-O-Stam * * * Adds Physical Endurance Reduces Muscle Soreness * * * Coach-Aid, Inc., P.O. Box 13355, Houston 19, Texas * * * Daily Dosage: 4 to 6 tablets for strenuous exercise 2 to 4 tablets for all others. Contents: A mixture of alkali, metal phosphates contained in natural body salts. Active Ingredients: Phosphate ph 6.5—7.0 Six tablets taken without exercise acts as a mild laxative" and "Coach-Aid Special Formula N.B. Pills (Bioflavonoids with C) * * * Capillary tablets to improve resistance to bruising, bleeding, and the 'Common Cold' Dosage: * * * Coach-Aid, Inc. * * * Houston 19, Texas."

LIBELED: 10–19–61, S. Dist. Fla.

CHARGE: (*Coach-Aid Stim-O-Stam tablets*), 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective for adding physical endurance, lessening muscle soreness, improving physical efficiency, and aiding in preventing fatigue; 502(e)(2)—the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since "Phosphate" is not the common or usual name for that ingredient; and (*Coach-Aid N.B. tablets*), 502(a)—the label contained false and misleading representations that the article was adequate and effective to improve resistance to bruising and bleeding, improve capillary resistance, overcome normal capillary permeability and fragility, prevent bleeding, strengthen capillary walls, reduce healing time and severity of bruises, improve formation of connected tissue and red blood cells, promote absorption of iron from food, and promote resistance to the common cold and virus and respiratory infections.

DISPOSITION: 11–24–61. Default—destruction.

6896. Juicex juice extractor. (F.D.C. No. 46617. S. No. 36–011 T.)

QUANTITY: 20 devices at Kenner, La., in possession of Southern Juicer Co.

SHIPPED: 8–16–61 and 8–18–61, from St. Clair Shores, Mich., by Drachenberg Products Manufacturing Co.

LABEL IN PART: (Device) "Juicex Vegetable & Fruit Juice Extractor * * * Model & Serial No. * * * Drachenberg Products Manufacturing Co., Detroit, Mich."

ACCOMPANYING LABELING: Folders entitled "Don't Suffer & Die in Despair"; books entitled "Raw Vegetable Juice–What's Missing in Your Body"; and leaflets entitled "Live Food Juices."

RESULTS OF INVESTIGATION: The inspector's photographs and labeling indicated that the juicer unit and liquifier attachment were not significantly unlike conventional portable electric motor-driven juice extractors designed for home use.

The leaflets entitled "Don't Suffer & Die in Despair" were shipped by Drachenberg Products Manufacturing Co.; the other leaflets were shipped from Arizona and California on order of the dealer.

LIBELED: 11–16–61, E. Dist. La.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a health aid in that its use would provide

vegetable juices which are beneficial to health where other healing methods fail, thus relieving suffering and despair of illness; that the article was of medical significance because it "is recommended by many doctors for results"; that "Raw fresh vegetable juices are full of health sustaining nutrients, whereas Cooked Foods are Dead Foods," thus the article, by reason of its use in extracting raw vegetable juices, serves as a health aid in the treatment of diabetes, arthritis, heart conditions, bladder tumors, eye trouble, leukemia, acne, colds, influenza, high blood pressure, cancer, boils, allergies, angina pectoris, kidney and liver disorders, anemia, asthma, appendicitis, low blood pressure, brain tumors, botulism, cataracts, colitis, deafness, diphtheria, epilepsy, goiter, Hodgkin's disease, impotence, polio, insanity, meningitis, pneumonia, prostate trouble and numerous other disease conditions.

DISPOSITION: 12–5–61. Consent—claimed by Mrs. Francis B. Thom, t/a Southern Juicer Co., and the accompanying literature destroyed.

6897. Niblack Home Pony device. (F.D.C. No. 45769. S. No. 55–774 R.)

QUANTITY: 5 devices at Seattle, Wash.

SHIPPED: Between 11–22–57 and 10–3–58, from Denver, Colo., by Niblack System, Inc.

ACCOMPANYING LABELING: Leaflets entitled "How To Keep Your Figure With The Niblack Home Pony," "Niblack System–The World's Greatest Method of Body Contouring," and "Niblack Slenderizing System Cordially invites you to visit our new salon . . ."; and a newspaper advertisement mat reading in part "Reduce At Home With the wonderful new Niblack 'Home Pony' * * * Take off inches while you catch up . . ."

RESULTS OF INVESTIGATION: Examination showed that the article was an appliance containing a series of rollers which were caused to rotate by a motor-driven belt. The patient was massaged by placing the rotating rollers against various portions of the anatomy.

LIBELED: 5–4–61, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for re-forming the body, removing surplus inches in specific areas of the body, keeping the body firm and vibrant, spot-reducing, contouring the body, relaxing tense nerves, correcting body defects, correcting body posture, reducing weight and removing unwanted inches, increasing circulation to remove wastes from the system, keeping the figure trim and firm after fat was removed, and strengthening muscles.

DISPOSITION: 12–11–61. Consent—claimed by A. T. Delcambre, Seattle, Wash., and relabeled.

6898. Leg rejuvenator device. (F.D.C. No. 46572. S. No. 15–708 T.)

QUANTITY: 5 ctnd. devices at Cincinnati, Ohio.

SHIPPED: 9–5–61, from Yonkers, N.Y., by Beacon Enterprises, Inc.

LABEL IN PART: (Ctn.) "Style #455 Leg Rejuvenator by Beacon Beacon Enterprises, Inc. 286 Fifth Ave., N.Y. 1, N.Y."

ACCOMPANYING LABELING: Leaflets entitled "Instructions For Assembling #455 Leg Lounger" and newspaper advertisement from 8–20–60 edition of The Cincinnati Enquirer, reading in part "Give a Lift To Your Legs and Heart with the Leg Rejuvenator by Beacon."

RESULTS OF INVESTIGATION: Examination showed that the article was a foot and leg rest constructed of metal tubing and plastic fabric.

LIBELED: 10–12–61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the use of the article was an adequate and effective treatment for heart strain, leg swelling, tension, fatigue, to stimulate leg circulation, for aching tired legs and feet, varicose veins, phlebitis, and to rejuvenate the legs.

DISPOSITION: 11–21–61. Default—delivered to the Food and Drug Administration.

6899. Airway '88' Sanitizor. (F.D.C. No. 45716. S. No. 25–863 R.)

QUANTITY: 3 devices at San Gabriel, Calif., and 40 devices at Los Angeles, Calif., in possession of Air-Way Sanitizor Sales and Service.

SHIPPED: 2–16–61, from Bloomington, Ill., by Airway, Inc.

LABEL IN PART: "Air-Way '88' Sanitizor."

ACCOMPANYING LABELING: Sales manuals entitled "Air-Way (Branches), Inc."; folders entitled "Defense against Disease"; booklets entitled "Air-Way '88' Sanitizor Owner's Guide"; and folders entitled "Air-Way '88' Sanitizor."

RESULTS OF INVESTIGATION: The labeling showed the article to be an upright tank-type vacuum cleaner equipped with a disposable dirt-collection bag and other conventional vacuum cleaner attachments.

LIBELED: 4–13–61, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective in removing streptococci organisms from the household and thereby preventing such infections as erysipelas, acute peritonitis, bronchopneumonia, meningitis, angina, mastoiditis, pleurisy, acute abscess, arthritis, septic sore throat, scarlet fever, pulmonary tuberculosis, smallpox, septic diphtheria, measles, tetanus and anthrax; and that use of the article prevented serious infections by removing such other organisms as staphylococci, gas formers, sarcinae, tetrads, nonhemolytic bacteria, hemolytic bacilli; protected health by eliminating the danger of contact with germ-laden dust and dirt; and reduced sickness from airborne infections, asthma, hay fever, and sinus conditions.

DISPOSITION: 5–31–61. Consent—claimed by Edwin H. Bartels, t/a Air-Way Sanitizor Sales and Service, and Air-Way Sanitizor, Inc., Toledo, Ohio, and relabeled.

6900. Electrode applicators. (F.D.C. No. 45939. S. Nos. 48–023/39 R.)

QUANTITY: 205 applicators at Ferndale, Mich., in possession of Renulife Electric Co.

SHIPPED: Between February 1957 and February 1961, from Chicago, Ill.

ACCOMPANYING LABELING: Leaflets entitled "Electrode Applicators For Use in Connection with Renulife Violet Ray Generators," "Health your most priceless asset," and "Instructions for Operating Renulife Violet Ray Health Generators."

RESULTS OF INVESTIGATION: Examination showed the article to comprise an assortment of sealed glass tubes of various sizes, shapes, or configurations, with a metal cap attached at one end. Some of the electrodes contained internal rods, wires, or discs.

The leaflets were printed locally on order of the dealer.

LIBELED: 6–19–61, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving fallen hair, dandruff, tonsilitis, goiter, prostate trouble, spinal conditions, eye, ear, and nose conditions, deafness, and vaginal inflammation; and for removing blemishes, scars, and warts.

DISPOSITION: 11–7–61; amended decree 11–15–61. Default—portions of the article and labeling delivered to the Food and Drug Administration and the remainder destroyed.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6861 TO 6900

PRODUCTS

[1] (6867) Injunction issued.

[2] (6874, 6888, 6894) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6867) Injunction issued.
[2] (6874, 6888, 6894) Seizure contested.

[1] (6867) Injunction issued.
[2] (6874, 6888, 6894) Seizure contested.

U.S. GOVERNMENT PRINTING OFFICE:1963

D.D.N.J., F.D.C. 6901–6960

Issued February 1963

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6901–6960

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, including, in one case, the entry of a decree of injunction and, in another case, the denial of a claimant's motion to open a default decree; and (2) criminal proceedings which were terminated upon pleas of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *February 21, 1963.*

CONTENTS*

*For an imitation of, and sale under name of, another drug, See No. 6940; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6911–6913, 6915, 6960; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6908, 6911–6915, 6923, 6958; cosmetics, actionable under the drug provisions of the Act, Nos. 6955, 6956.

672692—63——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6901–6960

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of acetophenetidin, atropine, hyoscine, and hyoscyamine contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, or bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DRUG AND DEVICE FOR HUMAN USE

6901. Fem-A-Line. (F.D.C. No. 46054. S. No. 87–083 R.)

QUANTITY: 33 4-oz. btls. and 3½ gals. at Dallas, Tex., in possession of Fem-A-Line Laboratories.

SHIPPED: The ingredients were shipped on various dates between 8–18–59 and 3–9–61, from outside the State of Texas.

LABEL IN PART: (Btl.) "Fem-A-Line A Medicinal Adjunct * * * Contains a Laxative * * * Active Ingredients: Fluid Extract Ergot, Tincture Hydras-

tis, and Tincture Aloe * * * Fem-A-Line Laboratories, 2716 North Henderson Dallas, Texas * * * Directions: Teaspoonful 30 minutes before meals and at bed-time in one-fourth glass of hot water * * * Avoid continuous use" and (reused gal. btls.) "Lactated Pepsin Not NF (the word 'Mixed' was handwritten across the label)."

ACCOMPANYING LABELING: Leaflets entitled "Fem-A-Line An Aid To Nature."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer from ingredients which had been shipped in interstate commerce. Some of the article was bottled and labeled and the remainder was stored in the gallon bottles labeled "Lactated Pepsin (Mixed)."

LIBELED: 8–17–61, N. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to assist retarded menstruation caused by severe colds or other unnatural suppression of the menses; 502(j)—the article was dangerous to health when used as directed in its labeling; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–1–61. Default—destruction.

6902. Glass syringes. (F.D.C. No. 46818. S. No. 18–317 T.)

QUANTITY: 1 doz. 2-cc. glass syringes at Palestine, Tex., in possession of Reynolds Clinic.

SHIPPED: On unknown dates, from outside the State of Texas.

ACCOMPANYING LABELING: Leaflets entitled "The Koch Treatment (Glyoxylide)," "Koch Diet," and "Order Form."

LIBELED: 11–21–61, E. Dist. Tex.

CHARGE: 502(f)(1)—the labeling failed to bear adequate directions for use; 502(f)(2)—the labeling failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of application; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its labeling.

DISPOSITION: 1–5–62. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6903. Medicated turkey feed (5 seizure actions). (F.D.C. Nos. 46276, 46422/5. S. Nos. 81–148/9 R, 81–395/9 R, 6–441 T.)

QUANTITY: 20 100-lb bags (crumbles), 310 100-lb. bags and 60 75-lb. bags (pellets), at Millis, Marlboro, Framingham Center, North Andover, and Lanesboro, Mass.

SHIPPED: Between 6–30–61 and 7–31–61, from Oneonta, N.Y., by Elmore Milling Co., Inc.

LABEL IN PART: (Tag) "Elmore Turkey Growing Mash Medicated (1H) * * * Active Drug Ingredients: 4-nitrophenylarsonic acid (Histostat) 0.025% * * * Manufactured by Elmore Milling Company, Inc., Oneonta, N.Y. (Pellets) [or "Crumbles"] [some bags bear another tag reading "Small" or "Pellets"]."

RESULTS OF INVESTIGATION: Examination showed that the article contained more than the declared amount of 4-nitrophenylarsonic acid.

LIBELED: 8–21–61, 8–29–61, and 8–30–61, Dist. Mass.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "4-nitrophenylarsonic acid (Histostat) 0.025%" was false and misleading as applied to a product which contained more than the declared amount of this ingredient; and 502(j)—the article was dangerous to the health of turkeys when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

DISPOSITION: 2–16–62. Consent—claimed by Elmore Milling Co., Inc., and released under bond to be brought into compliance with the law.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

6904. Vitamin B_{12}–B_1, Elixir Vinivita, and Expectogen. (F.D.C. No. 46942. S. Nos. 37–804/6 T.)

QUANTITY: 16 btls. of *Vitamin B_{12}–B_1*, 151 1-pt. btls. of *Elixir Vinivita*, and 203 1-pt. btls. of *Expectogen*, at Montgomery, Ala.

SHIPPED: Between 2–27–61 and 9–26–61, from St. Louis, Mo., by E. W. Heun Co.

LABEL IN PART: (Btl.) "Vitamin B_{12}–B_1 Each 5 cc. (1 teaspoonful) contains: Vitamin B–12, N.F. 25 mcg. Vitamin B–1 U.S.P. 10 mg. Manufactured for King Pharmaceutical Co., Inc., Montgomery 3, Alabama."; "King's One Pint Elixir Vinivita Improved Each 5 cc. (1 teaspoonful) contains: * * * Distributed by King Pharmaceutical Co., Inc., Montgomery, Alabama * * * Caution: Federal law prohibits dispensing without a prescription."; and "King's One Pint Expectogen For Relief of Coughs Due to Colds Each Fluid Ounce Represents: Dextromethorphan Hydrobromide 60 mg. Chlorpheniramine Maleate 12 mg. Potassium Guaiacol Sulfonate 8 gr. Ammonium Chloride 8 gr. Tartar Emetic 1/12 gr. Chloroform 2 min. * * * Distributed by King Pharmaceutical Co., Inc., Montgomery, Alabama. Dosage: Adults, orally 1 or 2 teaspoonsful every four hours as required. Children 6–12 years, one-half adult dose. For younger children consult physician."

LIBELED: 1–29–62, M. Dist. Ala.

CHARGE: (*Vitamin B_{12}–B_1*), 502(a)—when shipped, the bottle label contained false and misleading representations that the article was adequate and effective for promoting growth and appetite in a child who does not eat adequately or well; as an adjunct in treating the chronically ill or undernourished child; as a nutritional supplement in chronic diarrhea and celiac diseases; and for shortening convalescence through increasing the appetite; (*Elixir Vinivita*), 502(a)—the bottle label contained false and misleading representations that the article was adequate and effective as a treatment for or preventive of chronic fatigue, poor appetite, and iron and vitamin deficiencies; 503(b)(4)—the article was not subject to the provisions of 503(b)(1) and its label bore the statement "Caution: Federal law prohibits dispensing without prescription"; and (*Expectogen*), 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2–2–62. Consent—destruction.

6905. Twendex-PB timed disintegrating capsules. (F.D.C. No. 46912. S. No. 4–034 T.)

QUANTITY: 400 100-capsule btls. at Baltimore, Md.

SHIPPED: 5–11–60, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Capsules No. 118 Allison Twendex-PB Each Timed Disintegration Capsule contains: Dextro-Amphetamine Sulfate 20 mg. Phenobarbital 1 Gr. Warning: * * * Average: * * * Allison Laboratories, Inc., Baltimore, Maryland Distributors."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 99.5 percent of the declared amount of dextro-amphetamine sulfate and 98 percent of the declared amount of phenobarbital.

LIBELED: 1–18–62, Dist. Md.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2–8–62. Default—destruction.

DRUG FOR VETERINARY USE

6906. Medicated turkey feed. (F.D.C. No. 46566. S. No. 3–017 T.)

QUANTITY: 90 100-lb. bags at Laurel, Del.

SHIPPED: 10–13–61, from Baltimore, Md., by Sherwood Feed Mills, Inc.

LABEL IN PART: (Tag) "Sherwood Feeds 21% Turkey Grower Guaranteed Analysis * * * Medicated Active Drug Ingredient Amprolium 0.0125% (rubber stamped on label) Ingredients * * * Manufactured By Sherwood Feed Mills, Inc. Baltimore, Md. * * * 100 Lbs. Net Weight."

LIBELED: 10–16–61, Dist. Del.

CHARGE: 502(f)(1)—when shipped, the labeling failed to bear adequate directions for use; 502(f)(2)—the labeling failed to bear the required warning statements that medicated feed containing amprolium should not be fed to laying hens, and must be withdrawn 4 days prior to slaughtering the birds for food; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 1–31–62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

6907. Various antibiotic drugs. (F.D.C. No. 46963. S. Nos. 43–301/5 T.)

QUANTITY: 7,854 vials, packaged 10 vials to a box, of *procaine penicillin G in aqueous suspension;* 12,056 vials, packaged 10 vials to a box, 19,640 vials and 3,086 vials, of *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution;* and 10 ctns., each containing 10 vials of a commingled lot of *procaine penicillin G in aqueous suspension and procaine penicillin G in crystalline dihydrostreptomycin sulfate solution,* at Philadelphia, Pa.

SHIPPED: 8–1–61 and 8–14–61, from Des Moines, Iowa, and Mankato, Minn. These were return shipments.

RESULTS OF INVESTIGATION: Analysis showed that the *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* contained approximately (12,056-vial lot) 81 percent, (portion of 10-ctn. lot) 51 percent, and (19,640-vial lot) 82 percent of the declared amount of penicillin. The 7,854-vial lot of *procaine penicillin G in aqueous suspension* and the 19,640-vial lot and 3,086-vial lot of *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* bore labels containing expiration dates which had expired.

LIBELED: 2–8–62, E. Dist. Pa.

CHARGE: *Procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* (12,056-vial lot, 19,640-vial lot, and portion of 10-ctn. lot), 501(c)—when shipped and while held for sale, the strength of the article differed from that which it was represented to possess, namely, "Each 2 cc dose contains 400,000 units of crystalline procaine penicillin G."

502(l)—when shipped and while held for sale, the *procaine penicillin G in crystalline dihydrostreptomycin sulfate solution* (all lots) was composed in part of a kind of penicillin and of a streptomycin derivative, and the *procaine penicillin G in aqueous suspension* (all lots) was composed in part of a kind of penicillin, and such articles were not from batches with respect to which certificates or releases were in effect pursuant to 507 and the articles were not exempt from that requirement.

DISPOSITION: 4–18–62. Default—destruction.

6908. Various prescription drugs. (F.D.C. No. 46960. S. Nos. 54–861/72 T.)

QUANTITY: 2,671 tablets and capsules and 69½ pts. of liquid drugs at Jacksonville, Fla., in possession of Hermax Corp.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida and (some labels), the names and addresses of manufacturers, packers, or distributors outside the State of Florida.

LIBELED: 2–5–62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the statement "Professional Sample" or similar wording on the labels of a number of the articles was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—a number of the articles failed to bear labels containing the common or usual name of each active ingredient; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations; 502(l)—a number of the articles were drugs composed in whole or in part of a kind of penicillin, and were not from batches with respect to which certificates or releases were effective pursuant to 507 in that certification of the articles under their present labels had not been obtained; and 503(b)(4)—a number of the articles were subject to the provisions of 503(b)

(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3–7–62. Default—destruction.

DRUGS FOR VETERINARY USE

6909. Medicated feed. (F.D.C. No. 46853. S. No. 34–811 T.)

QUANTITY: 87 50-lb. bags at Colfax, N. Dak., in possession of Colfax Grain Co.

SHIPPED: 10–27–61, from Willmar, Minn.

LABEL IN PART: "Richland Quality 18% Pig Starter Medicated * * * Active Drug Ingredient Arsanilic Acid 0.0016%; Manganese Bacitracin 60 Grams Per Ton; Procaine Penicillin 20 Grams Per Ton Net Weight 50 Lbs. Manufactured by Colfax Grain Company, Colfax, North Dakota."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer from arsanilic acid shipped in interstate commerce as described above. Analysis showed that the article contained 6 times the labeled amount of arsanilic acid.

LIBELED: 12–14–61, Dist. N. Dak.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Arsanilic Acid 0.0016%" was false and misleading as applied to the article which contained an excess of that ingredient; 502(l)—the article was a drug composed in part of manganese bacitracin and procaine penicillin, and it was not from a batch with respect to which a certificate or release was in effect pursuant to 507 and it was not exempt from such certification since it contained less than the required amount of the active drug ingredient for the treatment of bacterial enteritis in swine for which it was intended, and in that the label failed to bear adequate directions and warnings for use by reason of failure on its label to bear the warning concerning the five day withdrawal prior to slaughter for human consumption, which warning was required by regulations for animal feeds containing an arsenical.

DISPOSITION: 3–2–62. Default—destruction.

6910. Medicated feed. (F.D.C. No. 46456. S. No. 6–008 T.)

QUANTITY: 30 100-lb. bags at Methuen, Mass.

SHIPPED: 7–14–61, from Deposit, N.Y., by Delaware Milling Co., Inc.

LABEL IN PART: "Pellets * * * Delaware Broiler Finisher Medicated * * * Active Drug Ingredients Dienestrol Diacetate 0.0035% Nicarbazin 0.0125% Arsanilic Acid 0.0090% * * * Feed Ingredients * * * Zinc Bacitracin * * * Manufactured by Delaware Milling Company, Inc. Deposit, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article contained only a trace of arsanilic acid.

LIBELED: 9–14–61, Dist. Mass.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Arsanilic Acid 0.0090%" was false and misleading when applied to the article which contained less than the declared amount of arsanilic acid; and 502(l)—the article contained dienestrol diacetate, nicarbazin, arsanilic acid, and zinc bacitracin, and they were not from batches with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 11–21–61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

6911. Amphetamine sulfate tablets. (F.D.C. No. 45558. S. Nos. 23–991 R, 24–251 R.)

INFORMATION FILED: 3–23–61, Dist. Kans., against John Richard Sallee.

ALLEGED VIOLATION: On 12–9–60, a number of unlabeled paper bags containing *amphetamine sulfate tablets* were caused to be shipped from Missouri to Kansas.

CHARGE: When shipped, the tablets failed to bear a label containing, 502(b)(1)—the name and place of business of the manufacturer, packer, or distributor; 502(b)(2)—an accurate statement of the quantity of contents in terms of numerical count; 502(e)(1)—the common or usual name of the drug; 502(f)(1)—adequate directions for use; 502(f)(2)—adequate warnings against use; and 503(b)(4)—the tablets were drugs subject to 503(b)(1) and they did not bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 6–8–61. 1 year imprisonment to run concurrently with the sentence imposed on the defendant as reported in notices of judgment on drugs and devices, No. 6961 (F.D.C. No. 45254).

6912. Various prescription drugs. (F.D.C. No. 45932. S. Nos. 36–112 R, 36–114/18 R.)

QUANTITY: 2 ctns., 3 shopping bags, and 8,149 btls., pkgs., and/or boxes, having an approximate total value of $5,000, at Palisades Park, N.J., in possession of Marshel Sales Co. (Samuel Udin).

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Complimentary," "Physician's Sample," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were unlabeled bottles which had been repacked by the dealer from physicians' samples received from various drug manufacturers' salesmen from outside the State of New Jersey. Some of the articles consisted of quantities of prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing "Caution: Federal law prohibits dispensing without prescription" and the words "Complimentary," "Physicians Sample," or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of New Jersey.

LIBELED: 6–9–61, Dist. N.J.; amended libel 6–13–61.

CHARGE: 502(a)—while held for sale, the statements "Complimentary," "Physicians Sample," and similar wording borne on the labels of the articles of drug which had not yet been repacked by the dealer were false and misleading as applied to such articles in possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the repacked articles of drug failed to bear a label containing (1) the

*See also Nos. 6901, 6904, 6908.

name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; 502(e)(1)—the repacked articles of drug failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the repacked articles of drug failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot number as required by regulations; 503(b)(4)—the repacked articles of drug failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–26–61. Default—destruction.

6913. Various prescription drugs. (F.D.C. No. 46457. S. Nos. 43/48 T.)

QUANTITY: 2,789 tablets and capsules and 42 btls. of liquids at Jacksonville, Fla., in possession of Fuqua's San Marco Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida and bearing the words "Professional Sample" or similar wording and the names and addresses of the manufacturers, packers, or distributors outside the State of Florida; quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of Florida; and quantities of prescription drugs in unlabeled containers.

LIBELED: 9–15–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the statement "Professional Sample" or similar wording on the labels of a number of the articles of drug was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the unlabeled articles of drug failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)(1)—the unlabeled articles of drug failed to bear labels containing the common or usual name of the drugs; 502(f)(1)—the labeling of the articles in unlabeled containers failed to bear adequate directions for use; and 503(b)(4)—the unlabeled articles of drug were subject to the provisions of 503(b)(1) and failed to bear labels containing the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–14–61. Default—destruction.

6914. Various prescription drugs. (F.D.C. No. 46094. S. Nos. 97–641/56 R, 97–659/60 R, 97–741/5 R.)

QUANTITY: 5,105 tablets and capsules in 202 boxes, folders, vials, and btls., at Erie, Pa., in possession of Eckerd's Kwik-Chek, Inc.

SHIPPED: Between 6–9–59 and 6–28–61, from Buffalo, N.Y., by Niagara Drug Co. of Buffalo, Inc., and on an unknown date by an unknown drug handler.

LABEL IN PART: (Some labels) "For Investigational Use Not to be Sold," "Professional Sample," "Complimentary," and "Physician's Professional Package."

LIBELED: 8–4–61, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the statements "Professional Sample," "Complimentary," "Physician's Professional Package," and similar wording on the labels of a number of the articles of drug were false and misleading as applied to articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians or others lawfully engaged in dispensing prescription drugs; and the statement "For Investigational Use Not To Be Sold" on the label of one of the drugs, when shipped, was false and misleading as applied to an article which was intended for sale and not intended for investigational use; 502(b)(1)—a number of the articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations; and 503(b)(4)—a number of the articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–16–61. Default—destruction.

6915. Various prescription drugs. (F.D.C. No. 46739. S. Nos. 12–881/3 T, 12–886 T, 12–888 T, 12–892 T, 12–894 T, 12–898/900 T.)

QUANTITY: Various quantities of tablets and capsules at Chicago, Ill., in possession of Solomon Cooper Drugs.

SHIPPED: On unknown dates, by various drug handlers.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Illinois, and the words "Physician's Sample," "Physician's Professional Package," "Professional Sample," "Complimentary," or similar wording; and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and bearing labels containing the words "Professional Sample," "Physician's Professional Package," "Sample Not To Be Sold," "Complimentary," or similar wording, and the names and addresses of the manufacturers, packers, or distributors located outside the State of Illinois.

LIBELED: 11–21–61, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the sample legends appearing on the labels affixed to the articles were false and misleading as applied to the articles in the possession of the repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs, and the labeling of a number of articles whose expiration dates had expired also was misleading as applied to the articles which were not suitable for use after their expiration date had expired; 502(b)—a number of the articles of drug failed to bear a label containing (1) the name and place of business of the manufacturer,

packer, or distributor and (2) an accurate statement of the quantity of contents; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations, and the labeling of a number of the articles whose expiration dates had expired also failed to bear adequate directions for use after their expiration dates; and 503(b)(4)—the articles of drug were subject to the provisions of 503(b)(1) and the labels of a number of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12–27–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6916. Amphetamine tablets and capsules. (F.D.C. No. 45434. S. No. 65–474 R.)

QUANTITY: Unknown quantities at Salemburg, N.C., in possession of DeWitt Clinton Bowman, t/a Carolina Drug Associates.

SHIPPED: Prior to 3–1–61, from outside the State of North Carolina.

LIBELED: 2–24–61, E. Dist. N.C.; amended libel 5–26–61.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended and the articles were not exempt from such requirement since they were not to be dispensed in accordance with 503(b).

DISPOSITION: 1–18–62 and 1–26–62. Default—delivered for use of various hospitals.

6917. Amphetamine tablets and capsules. (F.D.C. No. 45533. S. Nos 65–476/7 R.)

QUANTITY: Unknown quantities at Salemburg, N.C., in possession of DeWitt Clinton Bowman, t/a Carolina Drug Associates.

SHIPPED: Prior to 3–1–61, from outside the State of North Carolina.

LIBELED: 3–1–61, E. Dist. N.C.; amended libel 5–26–61.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended and the articles were not exempt from such requirements since they were not to be dispensed in accordance with 503(b).

DISPOSITION: 1–18–62. Default—delivered for use of a Federal hospital.

6918. Nutri-Bio food supplements. (F.D.C. No. 46814. S. Nos. 54–916 T, 55–001/4 T.)

QUANTITY: 213 ctns., containing 2 pkgs. of 13 plastic envelopes each; 53 ctns., 60 envelopes each; 48 ctns., containing 3 pkgs. of 8 envelopes each; 15 1-lb. pkgs. and 2 3-lb. pkgs., at Charlotte, N.C., in possession of T & G Enterprises.

SHIPPED: Between 8–1–61 and 11–30–61, from Beverly Hills, Calif.

LABEL IN PART: (213-ctn. lot) "Nutri-Bio dietary food supplement natural or organic Vitamins and Minerals from natural food sources * * * 728 Mineral Tablets 364 Vitamin Tablets"; (53-ctn. lot) "Nutri-Bio baby-bio 60 five gram Baby-Paks 300 grams net wt.; (48-ctn. lot) "Nutri-Bio * * * dietary

*See also Nos. 6902, 6908, 6911–6915.

food supplement Protein (meatless) In Ready-To-Eat Tasty Concentrated food Wafers 480 Wafers Lemon Flavor [or "Chocolate Flavor"] * * * the modern Nutri-Bio Carry-Pak * * * Each Carry-Pak contains 20 protein food wafers"; and (1-lb.-pkg. and 3-lb.-pkg. lots) "Nutri-Bio * * * Protein ready-to-use instant mix * * * 1 Lb. net wt. [or "3 Lb. net wt."]."

LIBELED: 12–27–61, W. Dist. N.C.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes and conditions for which they were intended, namely, the treatment and prevention of (*vitamins and minerals and baby-bio*) ulcers, colds, stiffness in fingers and joints, arthritis, loss of energy, poor circulation, nervousness, fever blisters, cancer, diabetes, overweight condition, tooth decay, gray hair, and incurable diseases, to prevent 75 percent of all diseases, and to extend life 10 to 20 years; (*Protein (meatless)* and *Protein instant mix*) loss of weight, excessive appetite, inadequate metabolism, tooth decay, to kill hunger pains, and to reduce, which were the conditions and purposes for which the articles were offered in oral statements made by William B. Gayle, a Nutri-Bio sales agent, in a sales talk at Charlotte, N.C.

DISPOSITION: 1–26–62. Default—portions of the articles were delivered to the Food and Drug Administration and the remainder was destroyed.

6919. Nutri-Bio food supplement. (F.D.C. No. 46608. S. No. 473 T.)

QUANTITY: 260 units and 14 units at Atlanta, Ga., in possession of Sherwood J. Gillespy, t/a V & S Sales Co., and Frank B. Wiggs, respectively. Each unit consisted of 2 ctns. enclosed in a cardboard sleeve, each ctn. containing 13 plastic envelopes of 14 tablets and 28 tablets each.

SHIPPED: 10–7–61, from Beverly Hills, Calif.

LABEL IN PART: (Ctn.) "Nutri-Bio * * * Dietary Food Supplement Vitamin and Mineral Tablets 364 Mineral Tablets 182 Vitamin Tablets * * * from natural food sources"; (sleeve) "Nutri-Bio dietary food supplement * * * the Nutri-Pak * * * Pocket carrier * * * contains a 7-day supply of Nutri-Bio. This package contains 26 nutri-paks"; and (envelope) "Your Seven-day supply of Nutri-Bio dietary food supplement natural or organic Vitamins & Minerals for the entire family."

LIBELED: On or about 10–25–61, N. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment and prevention of alcoholism, stomach ulcers, arthritis in the spine, tiredness, gray hair, gout, overweight and underweight, to put the body in absolute balance, and cancer, the conditions and purposes for which the article was offered in oral statements made on 10–5–61 and 10–6–61, by Frank B. Wiggs.

DISPOSITION: 12–4–61. No claimant having appeared, judgment of condemnation was entered and the article was ordered to be delivered, in part, to the Food and Drug Administration and the remainder to a public institution.

On 12–20–61, Frank B. Wiggs, claimant, filed a motion to open the default decree on the grounds that the wrong property was seized and impounded and that he, claimant, did not understand his rights relative to the libel and seizure of his property. On 1–16–62, the court entered the following order denying claimant's motion:

MORGAN, *District Judge:* "On October 25, 1961 the United States of America, through the United States Attorney for the Northern District of Georgia, filed a Libel of Information praying for the seizure and condemnation of a certain

article of drug which was said to be misbranded while held for sale after shipment in interstate commerce, within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352(f)(1).

"On December 4, 1961, this Court signed a default decree directing that the property against which the libel was filed should be destroyed, or, in lieu of destruction, that 30 units be turned over to the Food and Drug Administration for testing purposes, and the balance be turned over to the Georgia Penal System for use at the Georgia Industrial Institute, Alto, Georgia, to be dispensed by Dr. Hoston J. Walter.

"On December 20, 1961, the claimant to part of the articles seized in the above-styled libel filed a motion to open the default decree, contending that the wrong property was seized and impounded by the Deputy United States Marshal, and that he, claimant Frank B. Wiggs, did not understand his rights relative to the libel and seizure of his property and, therefore, unfortunately did not consult counsel to learn of and understand his rights prior to the entry of said decree by default.

"The Government opposes this motion of the claimant, and has filed a brief in support of its contentions.

"The Court feels that, since the decree of destruction has been complied with, the res of this in rem action is no longer before this Court. Inasmuch as this is an in rem action, the continued existence of the res is essential to the continuation of the action. If the goods are no longer before the Court and the decree has been carried out, the proceeding is completed, and any questions remaining unresolved are, therefore, moot, and there is nothing upon which the Court can act. *United States* v. *3 Unlabeled 25-pound bags . . . Mushrooms*, 157 F. 2d 722 (CCA 7, 1946); *Eureka Productions, Inc.* v. *Mulligan*, 108 F. 2d 760 (CCA 2, 1940).

"Further, default judgments or decrees are not to be opened in absence of a substantial showing of a meritorious defense to the libel and some explanation of reason why the default occurred. *North American Continental Co.* v. *The El Cuis*, 107 F. Supp. 436. In other words, the respondent must satisfactorily account for his laches.

"In view of the foregoing, it must be concluded that the explanation of why the default occurred is not sufficiently complete in that failure to seek legal advice can hardly be said to be an excusable event, and there also seems to be no substantial showing of the existence of a meritorious defense.

"The motion to open the default and allow filing of responsive pleadings is, therefore, denied.

"IT IS SO ORDERED."

6920. Rectal ointment and Tum-Tabs tablets. (F.D.C. No. 46771. S. Nos. 2–222 T, 2–802 T.)

QUANTITY: 116 individually ctnd. tubes of *rectal ointment* and 1 12,500-tablet drum and 5 100-tablet btls., of *Tum-Tabs tablets*, at Atlanta, Ga., in possession of Hussey Distributing Co.

SHIPPED: 4–23–61, from Philadelphia, Pa.

LABEL IN PART: (Ctn. and tube) "Net Wt. 1¼ Ozs. Husco Brand Rectal Ointment. Ingredients Phenol, Powdered Nutgall, Oil Tar, Pine Tar and isobutyl-para-aminobenzoate, in a Petrolatum base * * * Distributed by Hussey Distributing Co. Atlanta 3, Georgia"; (drum) "12,500 Tablets Magnalum Each Tablet Contains Magnesium Trisylicate 7½ gr. Aluminum Hydroxide Gel 4 gr. Aromatics q.s."; and (btl.) "100 Tum-Tabs Antacid-Absorbent Tablets Each Tablet contains * * * Distributed by Hussey Distributing Co. Atlanta, Ga."

ACCOMPANYING LABELING: Repack labels for *Tum-Tabs tablets*.

RESULTS OF INVESTIGATION: The *rectal ointment* was repacked by the dealer from bulk stock shipped on or about 5–1–61, from Philadelphia, Pa. The *Tum-Tabs tablets* were repacked by the dealer from the bulk stock of Magnalum, described above.

LIBELED: 12–5–61, N. Dist. Ga.

CHARGE: (*Tum-Tabs tablets*, bulk and repack), 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective in the treatment of peptic ulcers; and (*rectal ointment*), 502(f)(2)—the labeling failed to bear the warning "In case of rectal bleeding consult physician promptly."

DISPOSITION: 2–8–62. Default—destruction.

6921. Sea-Con. (F.D.C. No. 46750. S. No. 371 T.)

QUANTITY: 4 cases, 12 btls. each, at Charlotte, N.C.

SHIPPED: 8–29–61, from Columbia, S.C., by Sea-Con, Inc.

LABEL IN PART: (Btl.) "Contents One Pint Sea-Con Concentrated Ocean Water Sterilized Pasteurized Artificial Color Added Sea-Con is Highly Concentrated * * * prepared by Sea-Con, Inc., Columbia, S.C. * * * How to take Sea-Con Take one or two tablespoonsful daily * * * For a mild natural laxative effect" and (case) "Sea-Con A specially prepared concentration from the Sea. The only known source of all 44 water soluble trace elements Trace Elements Wonder of the Sea Nature's natural source of trace elements * * * You may add life to years add years to life."

LIBELED: 11–30–61, W. Dist. N.C.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations and suggestions that the article was of significant value for therapeutic use by reason of the presence of 44 trace elements; and that the article was adequate and effective to prolong life, prevent premature aging, and promote health; and 502(f)(2)—the labeling of the article, which was intended for use as a laxative, failed to warn that the article should not be taken when abdominal pain, nausea, or vomiting are present and that frequent or prolonged use of the article may result in dependence on laxatives.

DISPOSITION: 1–26–62. Default—24 btls. were delivered to the Food and Drug Administration and the remainder of the article was destroyed.

6922. Devine's products. (F.D.C. No. 45462. S. Nos. 36–871 R, 37–079 R, 38–041/3 R, 38–054/5 R.)

QUANTITY: 53 5-oz. tubes and 288 3-oz. tubes of *Kool-Foot;* 72 5-oz. tubes and 432 3-oz. tubes of *Ten Second Rub;* 288 cans of *Per-Fo;* 144 2-dram btls., 10 1-oz. btls., 2 8-oz. btls., and 10 ctns., each ctn. containing 1 3-oz. btl. and a plastic inhalator, of *Zina-Ray Oil;* and 720 envelopes, each containing one pad, of *Karbo-Silekon*, at Philadelphia, Pa., in possession of Miss Eleanor Callet.

SHIPPED: Between 11–17–60 and 1–5–61, from Chicago, Ill., by Devine's Remedies, Inc.

LABEL IN PART: (Tube) "Devine's KOOL-FOOT * * * Active Ingredients: Eucalyptus Oil—Antiseptic. Devine's Remedies, Inc., 4903 N. Ravenswood Chicago 40, Illinois,"; "Ten Second Rub * * * Active Ingredients: Lanolin, Menthol, Eucalyptus Oil, Peppermint Oil, and Pine Needle Oil * * * Devine's Remedies, Inc., Chicago 40, Illinois"; (some cans) "Devine's PER-FO * * * Directions: * * * Contains: Alkaline Forate of Sodium USP, Phosphate Tri Sodium (Fines), Natural Pine Needle Oil USP 6.07 oz. weight."; "Improved

Devine's PER-FO * * * Directions: * * * Contains: Alkaline Borate of Soda, Sodium Tripolx Phosphate, Sodium Sesquicarbonate, Sodium Alkul Aryl Sulfonate, Natural Pine Needle Oil U.S.P. 3¾ Ozs. Weight Devines Remedies, Inc."; (btl.) "Devine's Zina-Ray Oil * * * Contains—Eucalyptus Oil, Menthol, Pine Needle Oil and Peppermint Oil. * * * Devine's Remedies"; and (envelope) "Devine's KARBO-Silekon Direction * * * Devine's Karbo Silekon is a combination of carbon and silicon baked on a waterproof material. * * * Devine's Remedies, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Feet Hurt Burn . . . Tired . . . Itch . . . Ache????? Then use Devine's Kool-Foot For One Minute . . ."

RESULTS OF INVESTIGATION: Examination showed that the "inhaler" consisted of a round glass vial approximately 2½'' long and ½'' in diameter, with small openings at both ends and containing a small amount of absorbent cotton.

LIBELED: 2–9–61, E. Dist. Pa.

CHARGE: *Kool-Foot*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for athlete's foot.

Ten Second Rub, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for headache, colds, and cough.

502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Kool-Foot*) for preventing or treating foot trouble; (*Per-Fo* and *Improved Per-Fo*) for helping blood circulation and for treating foot trouble; (*Zina-Ray Oil*) for treating colds, preventing grippe, pneumonia, and flu, and for treatment of colds, coughs, sneezing, headache, and sinus trouble; (*Ten Second Rub*) for treatment of asthma, rheumatism, arthritis, sinus trouble, lumbago, sciatica, catarrh, headache, poor circulation, stiff joints, stiff necks, backache, leg cramps, croup, cough, and chest colds; and (*Karbo-Silekon*) for permanently removing corns and callouses, which were the conditions and purposes for which the articles were offered and recommended orally by Eleanor Callet, demonstrator, during the course of a lecture, on 11–30–60, at W. T. Grant Store, 11th and Market Street, Philadelphia, Pa.

DISPOSITION: 2–7–62. Default—destruction.

6923. Blood and nerve tonic, cough syrup, and liver-kidney regulator. (F.D.C. No. 46906. S. Nos. 25–141/3 T.)

QUANTITY: 32 16-oz. btls. of *blood and nerve tonic*, 115 4-oz. btls. of *cough syrup*, and 82 6-oz. btls. of *liver-kidney regulator*, at Benton Harbor, Mich.

SHIPPED: 10–15–61, from Gary, Ind., by Red Mountain Medical Co.

LAREL IN PART: (Btl.) "Red Mountain Blood and Nerve Tonic"; "The Famous Red Mountain Cough Syrup"; "Red Mountain Liver-Kidney Regulator"; (each btl. also labeled) "Mfd. by Red Mountain Medical Co. Dr. B. J. Cockrell Mfg. Chemist."

LIBELED: 1–8–62, W. Dist. Mich.

CHARGE: (*Blood and nerve tonic*), 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for promoting pep, vigor, and energy, for rundown nerves, impure blood, rheumatism, anemia, bladder weakness, swelling and stiffness of lower limbs and joints, skin diseases, and loss of appetite; and the

labeling contained false and misleading representations that another drug, *Red Mountain Liver-Kidney Regulator*, was adequate and effective as a treatment for biliousness, poor digestion, acid stomach, colds, kidney and back troubles, and general elimination of body waste and poisons; 502(b)(1)—the label failed to bear the name of the place of business of the manufacturer; and 502(f)(2)—the label listed potassium iodide as an active ingredient and failed to bear the warning statement required for oral preparations containing iodides, "If a skin rash appears, discontinue use and consult physician"; (*cough syrup*), 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for coughs (unqualified), colds (unqualified and most severe), bronchial irritations, tight stuffy chest due to colds and exposure, and hoarseness; and the label contained false and misleading representations with reference to another drug, *Red Mountain Liver and Kidney Regulator Laxative*, that the use of the two drugs was adequate and effective as a treatment for deeply seated colds; (*liver-kidney regulator*), 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for eliminating wastes and poisons from the system, relief of sluggish liver and kidneys, backaches, headaches, colds, constipation (unqualified), indigestion, gastric stomach, dizziness, high blood pressure, bad breath, no pep due to a bilious system, and to prevent serious menstrual pain; and the label contained false and misleading representations that another drug, *Red Mountain Blood and Nerve Tonic* was an adequate and effective treatment for the suffering of nervousness, rheumatism, impure blood, general rundown condition, and for toning and pepping up the system; and the label paragraph "General Directions" contained a statement which directed use of the product continuously, "2 to 3 times per week," which statement was false and misleading since it was contrary to the label warning statement "Caution: Frequent usage may result in laxative dependency"; and 502(f)(2)—the label declared the presence of the active laxative ingredient, phenolphthalein, and its label failed to bear the required phenolphthalein warning statement, "Caution: If skin rash appears do not use this or any other preparation containing phenolphthalein."

DISPOSITION: 2–12–62. Default—destruction.

6924. E-Hi capsules and Isomar tablets. (F.D.C. No. 45663. S. Nos. 19–982 R, 36–731 R.)

INFORMATION FILED: 12–19–61, S. Dist. Calif., against McCollum Laboratories, Inc., North Hollywood, Calif., Edward McCollum, president, and Florence McCollum, secretary-treasurer.

SHIPPED: 3–3–60 and 4–15–60, from California to Pennsylvania and Ohio.

LABEL IN PART: (Ctn.) "McCollum E-Hi Capsules * * * High Potency Source of Vitamin E * * * Made from Natural Vegetable Oils" and "Isomar * * * 150 Tablets * * * Distributed by McCollum Laboratories, Inc. Hollywood 28, Calif."

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely (*Isomar tablets*), for the treatment and prevention of tiredness, indolence, cold hands and feet, loss of agility of mind, and sluggish memory; to build blood, and to keep blood in first class condition; and to produce vitality, warmth, proper tissue tone, and strength; and (*E-Hi capsules*), for the treatment and prevention of coronary heart

trouble, heart attacks, asthma, reduced blood pressure, diabetes and decreased need for insulin in diabetes, diseases of the glands, underactive thyroid, difficult menopause, female complaints, blood diseases, inflamed veins in the legs, leg cramps, and falling hair.

PLEA: Corporation and Florence McCollum—guilty to both counts of information; Edward McCollum—guilty to one count.

DISPOSITION: 2–20–62. Corporation—$200 fine; Florence McCollum—$200 fine; Edward McCollum—$100 fine.

6925. Controcal. (F.D.C. No. 45721. S. No. 19–840 R.)

QUANTITY: 6,158 cases, 24 5-oz. cans each, at Detroit, Mich., in possession of Milk Proteins, Inc.

SHIPPED: Between 11–11–60 and 2–3–61, from Barrington, Ill.

LABEL IN PART: (Can) "Controcal Controls Calories Complete Balanced Concentrated Food For Weight Control Formula #2–to be mixed with skim milk nutritious . . . and it tastes good * * * Controcal dietary for weight control * * * A complete balanced food–high grade milk protein, vitamins and minerals * * * controls calorie intake while supplying adequate nutrition and appetite satisfaction. Weight loss is achieved comfortably and pleasantly by the low calorie intake. * * * Milk Proteins Inc. Detroit 16, Michigan * * * Ingredients: * * * When the contents of this can (5-oz.) are added to 1 quart of skim milk, the following nutrients are supplied: Calories 900; Protein, gm. 72; Fat, gm. 21; Carbohydrate, gm. 112; Minerals, gm. 14.5; Vitamin A, units 5000; * * * Vitamin C, mg. 100; Thiamin, mg. 2; Riboflavin, mg. 3; * * * Calcium, gm. 3.9; Phosphorus, gm. 2.9; * * * Minimum Daily Requirements (adults)."

ACCOMPANYING LABELING: Folders entitled "Controcal Promotion Kit."

RESULTS OF INVESTIGATION: The article was manufactured by Milk Proteins, Inc., and sent to Barrington, Ill., for packaging. The accompanying labeling was printed at Omaha, Nebr., on order of Milk Proteins, Inc.

LIBELED: 4–19–61; amended libel 5–1–61, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective to promote full, vigorous health, promote growth in boys and girls, prevent decline in health, excessive fatigue, and susceptibility to colds and other contagious diseases; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in losing, maintaining, and gaining weight, and in controlling weight.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2–20–62 and 2–26–62. Default—delivered to a charitable institution.

6926. Menstrual pain relief tablets, Barosil, and Barogel. (F.D.C. No. 46232. S. Nos. 74–854 R, 74–857/8 R.)

QUANTITY: 1 14,000-tablet bulk drum and 9 individually ctnd. repack btls. of *menstrual pain relief tablets;* 12 1-gal. bulk btls., 7 1-gal. repack btls., and 3 1-qt. repack btls. of *Barosil;* 16 1-gal. bulk btls., 4 1-gal. repack btls., and 2 1-qt. repack btls. of *Barogel,* at Coral Gables, Fla., in possession of Barry-Martin & Co.

SHIPPED: Between 7–21–60 and 4–12–61, from Chicago, Ill., and Brooklyn, N.Y.

LABEL IN PART: (Btl. and ctn.) "Barry-Martin Menstrual Pain Relief * * * Tablets Distributors Barry-Martin & Co., Miami 46, Fla. * * * Each tablet contains: Salicylamide, Phenacetin, Phenylpropanolamine HCl Hyoscyamine HBr, Atropine Sul., Hyoscine HBr, Mag. Glycinate."; (repack btl.) "Barosil * * * One teaspoonful contains Magnesium Trisilicate 0.5 Gm. (7.5 Grains) Aluminum Hydroxide 0.25 Gm. (4.0 grains) * * * Distributors Barry-Martin & Co., Miami, Florida"; (repack btl.) "B–M * * * Barogel Amphoteric Aluminum Hydroxide Gel."

RESULTS OF INVESTIGATION: The bulk lots of articles described above were repacked by the dealer into the bottles described above.

LIBELED: 9–1–61, S. Dist. Fla.

CHARGE: (*Barosil* and *Barogel*), 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that they were adequate and effective for the management of peptic ulcers; (*menstrual pain relief tablets*), 502(e)(2)—the article was a drug fabricated from two or more ingredients, and its label failed to bear the quantity or proportion of phenacetin (acetophenetidin), hyoscyamine, atropine, and hyoscine contained therein; and 502(f)(2)—the labeling failed to bear the warning statements for preparations containing belladonna alkaloids: "Not to be used by elderly persons or by children under 6 years of age unless directed by physician" and "Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs" and the warning statement for preparations containing phenylpropanolamine hydrochloride: "Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician."

DISPOSITION: 2–26–62. Consent—claimed by Barry-Martin & Co. and released under bond for relabeling.

6927. Paregoric. (F.D.C. No. 46925. S. No. 54–621 T.)

QUANTITY: 41 cases, 12 2-oz. btls. each, 98 cases, 12 1-oz. btls. each, and 66 cases, 12 ½-oz. btls. each, at Atlanta, Ga., in possession of Southern Druggists, Inc.

SHIPPED: 1–15–62, from Memphis, Tenn.

LABEL IN PART: (Btl.) "Ev-R Pure Brand Paregoric U.S.P. Anhydrous Morphine 0.35 to .045 Gm in 100 cc. * * * Directions: 3 days old, 1 drop; 1 week old, 2 drops; 1 month old, 3 drops; 1 year old, 8 drops; 5 years old, 20 drops. Adults a teaspoonful. * * * Packed by Tolleson Laboratories, Atlanta, Georgia."

RESULTS OF INVESTIGATION: The article was shipped in gallon bottles and repacked by the dealer into the bottles described above.

LIBELED: 1–17–62, N. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in that it did not state the conditions and purposes for which the article was intended to be used, and in that the directions for use for infants were improper.

DISPOSITION: 2–26–62. Default—destruction.

6928. Skin salve. (F.D.C. No. 46940. S. No. 55–915 T.)

QUANTITY: 13 ctns., 12 2-oz. jars each, at Hackensack, N.J.

SHIPPED: 10–5–61 and 11–16–61, from New York, N.Y., by Ko-Jo, Inc.

LABEL IN PART: (Jar) "Koch's Guaranteed Skin Salve * * * Contains Petrolatum and Sulphur Ointment * * * Ko-Jo, Inc., Dist. New York."

LIBELED: 1–29–62, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment of burns, scalds, acne, eczema, ringworm, impetigo, fungus growth, and diaper rash; and 502(f)(2)—the article contained sulphur and the labeling failed to bear the warning statement that if undue skin irritation developed or increased, use of the article should be discontinued and a physician consulted.

DISPOSITION: 3–12–62. Default—destruction.

6929. One Day Pac Aids. (F.D.C. No. 46602. S. Nos. 26–371/6 T.)

QUANTITY: 1 500-packet case of *Aspirin Plus;* 1 500-packet case of *Acidamol;* 1 500-packet case of *Calcontrol;* 1 500-packet case of *Vitaffeine;* 1 500-packet case of *Clair-nasal;* and 1 500-packet case of *Bromidamin*, at Detroit, Mich.

SHIPPED: 1–13–61, from Chicago, Ill., by F. A. Products Co.

LABEL IN PART: (Packet) "Aspirin Plus * * * contains four tablets. Each tablet contains: 3.5 grs. Aspirin, 2.5 grs. Acetophenetidin, 0.5 grs. Caffeine, 1.0 mg. Vitamin B_1"; "Stomach Relief (Acidamol) * * * contains two tablets * * * Active Ingredients: Aluminum Hydroxide, Magnesium Trisilicate"; "Calorie Control (Calcontrol) * * * contains two tablets. Each tablet contains: Guar Gum, Saccharine, and Sucaryl"; "Alertness (Vitaffeine) * * * Vitaffeine is composed of 17 ingredients with concentrates of Vitamin B_1, Vitamin C, Caffeine and iron * * * contains two tablets"; "Cold-Sinus (Clair-nasal) * * * contains four tablets. Each tablet contains: 5 grs. Apan (N-Acetyl-P-Aminophenol), 15 mg. Phenyl Propanolamine HCl, 6 mg. Phrilamine Maleate, Hesperidin Complex, 30 mg. Vitamin C; and "Calm Nerves (Bromidamin) * * * contains two tablets. Each tablet contains: 7.5 grs. Calcium Bromidogalactogluconate, 1.0 mg. Vitamin B_1, 1.2 mg. Vitamin B_2, 0.1 mg. Pyridoxine HCl, 10.0 mg. Niacinamide, 5.0 mg. Calcium Pantothenate."

LIBELED: 10–26–61, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective (*Acidamol*) for "stomach relief" and "upset stomach," (*Calcontrol*) for calorie control and thereby resultant weight control, and that it had appetite appeasing properties, (*Clair-nasal*) as a treatment for colds (unqualified) and sinus congestion, (*Bromidamin*) as a treatment for sleeplessness, nervous tension, and irritability, and (*Vitaffeine*) the label statement "a natural stimulant for vitality and alertness" was false and misleading, since the article was not "natural" and was not adequate and effective for the purposes for which it was recommended; (*Aspirin Plus*), 502(e)(1)—the label failed to bear the common or usual name of the drug; and 502(f)(2)—the article was offered for use in the treatment of rheumatism and arthritis and its labeling failed to bear the warning statement "Caution–if pain persists for more than 10 days or redness is present consult a physician immediately."

DISPOSITION: 3–22–62. Default—destruction.

6930. Carrot juice, celery root juice, and beet juice. (F.D.C. No. 46402. S. Nos. 55–784/6 R.)

QUANTITY: 71 cases, 6 btls. of carrot juice each; 45 cases, 6 btls. of celery root juice each; and 4 cases, 6 btls. of beet juice each, at Seattle, Wash., in possession of Dorwin Cook.

SHIPPED: 6–9–61, from New York, N.Y.

LABEL IN PART: (Btl.) "A Sparkling Toast to You from Switzerland Biotta Pure Carrot Juice [or "Celery Root Juice" or "Beet Juice"] bottled with Dr. F. Keitel's Lacto Fermentation Method utilizing vegetable lactic acid bacteria to produce juices with that Fresh Sparkling Uncooked taste. * * * Produced and Bottled by Gemosebau ag Tagerwilen, Switzerland U.S. Importer Dorwin Cook * * * Net Contents: 1 pt. 3 fl. ozs."

ACCOMPANYING LABELING: Reprints from the magazine "Let's Live," entitled "The Benefits Obtainable from Using Lacto-Fermented Vegetable Juices, by Dr. Fritz Caspari."

RESULTS OF INVESTIGATION: The above-mentioned reprints were ordered by the dealer to be printed and were used by him in promoting sales of the articles.

LIBELED: 8–25–61, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations and suggestions that the articles were adequate and effective for the treatment and prevention of fatigue, obstipation, chronic disturbances of the gastrointestinal tract, unspecified dermatoses, nervous and overstrained conditions, obesity, liver and gallbladder conditions, anemia, improper blood pressure, rheumatism, cardiac conditions and cancer, and for other purposes; and 502(f)(1)—the labeling failed to bear adequate directions for use in the treatment and prevention of chronic and infectious diseases, stomach, gallbladder, and liver trouble, cancer, fatigue, obstipation, obesity, nervous and overstrained conditions, chronic disturbances of the gastrointestinal tract, unspecified dermatoses, anemia, improper blood pressure, rheumatism, cardiac conditions, colds, and for other purposes which were the diseases and conditions for which the articles were intended and for which they had been described, recommended, and suggested.

DISPOSITION: 2–5–62. Default—delivered to a public institution.

6931. Figurette massage table. (F.D.C. No. 43269. S. No. 52–000 P.)

QUANTITY: 21 ctnd. devices at Minneapolis, Minn., in possession of Lucky-Lu Enterprises.

SHIPPED: 4–27–59 and 5–12–59, from Grand Prairie, Tex., by A.R.A. Manufacturing Co.

LABEL IN PART: (Device) "Figurette."

ACCOMPANYING LABELING: Pamphlets entitled "The Sure Way Figurette" and "Figurette Training Program."

RESULTS OF INVESTIGATION: The labeling and inspector's photographs indicated that the article consisted of a box-shaped housing containing an electric motor capable of providing vibration to two upholstered pads attached above the housing. Collapsible foot and head rests extended from the ends of the rectangular-shaped housing.

LIBELED: 6–19–59, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for reproportioning the entire body, relieving many daily tensions, correcting posture, stimulating circulation, tightening and toning muscle tissues, removing excess fatty tissue, and reducing and slenderizing; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, the treatment of bursitis, rheumatism, arthritis, rheumatic fever, slipped disc, and high blood pressure, which were the conditions and purposes for which the article was offered in oral statements by the sales representative, Mrs. Mary E. Shaffer.

DISPOSITION: On 7–1–59, the case was removed to the Southern District of Texas. On 5–19–61, A.R.A. Manufacturing Co., claimant, having consented, the court entered a decree of condemnation and destruction and the objectionable literature was destroyed.

6932. Violet ray generator device. (F.D.C. No. 45940. S. No. 20–531 R.)

QUANTITY: 14 devices at Sandusky, Ohio, in possession of New Life, Inc.

SHIPPED: 1–23–61, from Ferndale, Mich., by Renulife Electric Co.

LABEL IN PART: "Renulife Violet Ray Generator Made * * * by Renulife Elec. Co., Ferndale, Mich. No. 258 (or other numbers) Model No. 2."

ACCOMPANYING LABELING: Leaflets entitled "Instructions for Operating Renulife Violet Ray Health Generators" and "Health your most priceless asset."

RESULTS OF INVESTIGATION: The literature indicated the device to be a black grain leatherette case, 4½" x 10½" x 11½", containing a control panel, three electrodes, and a plastic tubular-shaped applicator connected to the control panel by an electric cord. The three electrodes, made of metal and glass, were in the shape of a tube, bulb, and rake, which plug into the ends of the applicator. The electronic circuiting was probably a tesla coil.

The leaflet entitled "Health your most precious asset" was printed locally.

LIBELED: 6–7–61, N. Dist. Ohio.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving arthritis, bursitis, dandruff, eczema, rheumatism, acne, nervous conditions, neuralgia, neuritis, sciatica, and poor circulation; and that the article functioned to aid nature in performing various bodily responsibilities; and 502(f)(1)—when shipped, its labeling failed to bear adequate directions for use in that the labeling failed to state the diseases and conditions for which the article was intended.

DISPOSITION: On 7–5–61, New Life, Inc., claimant, filed an answer denying that the article was misbranded. Thereafter, on 11–14–61, the claimant having consented, the court entered a decree of condemnation and the article was delivered to the Food and Drug Administration.

6933. Vacuum cleaning device. (F.D.C. No. 46429. S. No. 2–042 R.)

QUANTITY: 51 devices at Atlanta, Ga.

SHIPPED: Between 8–1–58 and 8–28–61, from Syracuse, N.Y.

RESULTS OF INVESTIGATION: Examination indicated that the article was a canister-type vacuum cleaner equipped with various attachments, including a water reservoir.

LIBELED: 8–30–61, N. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the prevention of infectious and parasitic diseases such as tuberculosis, meningitis, influenza, tonsillitis, erysipelas, and osteomyelitis, cancer, colds, and infections due to staphylococcus and streptococcus germs which were the diseases, conditions, and purposes for which the article was offered in oral statements made by Bill Hammond, salesman for Rexair Advertising of Atlanta, Inc., on or about July 27, 1961, at Decatur, Ga., in the presence of a Food and Drug Administration inspector.

DISPOSITION: On 11–27–61, Rexair Advertising of Atlanta, Inc., claimant, filed an intervention and claim to the article denying the allegations of misbranding of the libel and, without admitting that the article was misbranded while held for sale after shipment in interstate commerce, or was held illegally within the jurisdiction of the court, consented to the entry of a decree of condemnation, a decree of injunction, and a decree permitting the repossession and disposition of the article by the claimant under Government supervision.

On 12–6–61, a consent decree of condemnation and injunction was entered which permitted the repossession and bringing of the article into compliance with the law. The decree further enjoined the claimant and its officers, agents, employees, representatives, and all or any other person in active concert or participate with it or any of them from doing the following acts:

(a) Introducing into interstate commerce any "Rexair" cleaning device, any vacuum cleaning machine, or any other cleaning device, which is represented to be useful in the diagnosis, cure, mitigation, or prevention of infectious and parasitic diseases, tuberculosis, meningitis, influenza, tonsillitis, erysipelas, osteomyelitis, cancer, colds, staphylococcus and streptococcus infections, or any other disease or abnormal health condition of man;

(b) Doing any act with respect to the "Rexair" cleaning device, any vacuum cleaning machine or any other cleaning device, while such article is held for sale after shipment in interstate commerce, which will result directly or indirectly in said article being represented to be useful in the diagnosis, cure, mitigation, treatment, or prevention of infectious and parasitic diseases, tuberculosis, meningitis, influenza, tonsillitis, erysipelas, osteomyelitis, cancer, colds, staphylococcus and streptococcus infections, or any other disease or abnormal health condition of man.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICE FOR HUMAN USE*

6934. Liver-folic acid. (F.D.C. No. 46867. S. No. 31–394 T.)

QUANTITY: 10 individually ctnd. 10-cc. vials at Temple City, Calif.

SHIPPED: 10–1–61, from Philadelphia, Pa.

LABEL IN PART: (Vial and ctn.) "10 cc Multiple-Dose Vial Liver-Folic Acid Vitamin B–12 60 mcgm. (Crystalline) Folic Acid 5 mg. Lot No. 1469."

*See also No. 6907.

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 50 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–29–61, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Vit. B–12 60 mcgm." was false and misleading.

DISPOSITION: 1–25–62. Default—destruction.

6935. Liver injection (crude) and Liv-I-Plex injection. (F.D.C. No. 46612. S. Nos. 30–163/4 T.)

QUANTITY: 80 30-cc. vials of *liver injection (crude)* and 104 30-cc. vials of *Liv-I-Plex injection*, at Phoenix, Ariz.

SHIPPED: On 4–26–60 and 11–30–60, from Los Angeles, Calif., by Injectable Pharmacal Co.

LABEL IN PART: (Vial of liver injection) "Sterile Multiple Dose Vial Liver Injection (Crude) USP Each cc. contains Vitamin B_{12} activity equivalent to 2 micrograms of cyanocobalamin Rocky Mountain Pharmacal Co. Phoenix, Arizona Distributors"; (ctn. of Liv-I-Plex) "Sterile Multiple Dose Vial Liv-I-Plex Fortified Each 2 cc contains: Liver Injection USP 0.1 cc Folic Acid 2 mg. Iron Peptonized 59 mg. Pyridoxine H.C.L. 0.3 mg. Riboflavin 0.3 mg. Sodium Citrate 1% Niacinamide 50 mg. Phenol 0.5% Vitamin B_{12} Cryst. 30 mcgm. Procaine 1% Distributed by Rocky Mountain Pharmacal Co."; and (vial of Liv-I-Plex) "Sterile Multiple Dose Vial Liv-I-Plex Forte Each cc represents Vitamin B–12 activity (from liver injections, U.S.P. 10 mcgm. per cc) equivalent to: Cyanocobalamin 2 Mcgm. Vitamin B–12 (Crystalline, U.S.P.) 15 Mcgm. Peptonized Iron 20 Mg. Thiamine Hydrochloride, U.S.P. 10 Mg. Riboflavin, U.S.P. 0.5 Mg. Pyridoxine Hydrochloride 1.0 Mg. Panthenol 1.0 Mg. Niacinamide USP 10 Mg. Sodium Citrate, U.S.P. 1.0% Procaine Hydrochloride U.S.P. 0.5% Rocky Mountain Pharmacal Co."

RESULTS OF INVESTIGATION: Analysis showed that the article, *liver injection (crude)*, contained 225 percent of the declared potency of vitamin B_{12}. The National Formulary permits a variation in strength for *liver injection (crude)* up to 150 percent of the potency stated on the label.

The *Liv-I-Plex injection* was in a vial bearing a label which differed from the label on the carton.

LIBELED: 11–9–61, Dist. Ariz.; amended libel 12–1–61.

CHARGE: *Liver injection (crude)*, 501(b)—when shipped, the article purported to be *liver injection (crude)*, a drug, the name of which was recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium since, when assayed in accordance with the method prescribed in the National Formulary, the article contained 225 percent of the potency of its labeled amount of cyanocobalamin; 502(a)—the label statement "Each cc. vitamin B_{12} activity equivalent to 2 micrograms of cyanocobalamin" was false and misleading as applied to a product containing more than the labeled amount of vitamin B_{12}; and the label statement "Liver Injection (Crude) U.S.P." was false and misleading since the article was recognized in the National Formulary and not in the United States Pharmacopeia, as such label statement represented.

Liv-I-Plex injection, 502(a)—the vial label and the carton label bore statements concerning the composition of the article which were false and mislead-

ing since the composition of the article as declared on the carton label differed in identity and strength from the composition as declared on the vial label.

DISPOSITION: 1–26–62. Default—destruction.

6936. Benat with B_{12} injection. (F.D.C. No. 46979. S. No. 30–890 T.)

QUANTITY: 333 ctnd. vials at East Los Angeles, Calif.

SHIPPED: 9–1–61, from Philadelphia, Pa.

LABEL IN PART: (Ctn. and vial) "10 Ml. Multiple Dose Vial Benat With B_{12} For Intramuscular Injection * * * Each Ml. Contains: * * * Thiamine HCl 10 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 75 percent of the declared amount of thiamine hydrochloride.

LIBELED: 1–12–62, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each Ml. contains * * * Thiamine HCl 10 mg." was false and misleading.

DISPOSITION: 2–9–62. Default—destruction.

6937. Li-Fo-B-12. (F.D.C. No. 46928. S. No. 215 T.)

QUANTITY: 52 ctnd. vials at Miami, Fla.

SHIPPED: 4–26–61, from New Rochelle, N.Y.

LABEL IN PART: (Ctn. and vial) "10 cc. Multiple Dose Vial Li-Fo-B-12 Each cc. contains * * * Vitamin B_{12} U.S.P. Crystalline 30 mcg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 25 percent of the declared amount of vitamin B_{12}.

LIBELED: 1–22–62, S. Dist. Fla.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each cc. contains * * * Vitamin B_{12} U.S.P. Crystalline 30 mcg." was false and misleading.

DISPOSITION: 2–28–62. Default—destruction.

6938. Pas-C powder. (F.D.C. No. 46642. S. No. 13–302 T.)

QUANTITY: 2 50-lb. drums at Chicago, Ill.

SHIPPED: 4–17–61, from New York, N.Y., by Hexagon Laboratories.

RESULTS OF INVESTIGATION: Analysis showed that the article was para-aminosalicylic acid and not para-aminosalicylic ascorbate as represented.

LIBELED: 11–17–61, N. Dist. Ill.

CHARGE: 501(d)(2)—when shipped, para-aminosalicylic acid had been substituted for para-aminosalicylic ascorbate; 502(a)—the label statement "PAS-C" was false and misleading when applied to an article which contained no ascorbic acid (vitamin C).

DISPOSITION: 3–5–62. Consent—claimed by Hellwig, Inc., Chicago, Ill., without admitting the allegations of adulteration and misbranding, and relabeled.

6939. Ergonovine maleate tablets. (F.D.C. No. 46900. S. Nos. 79–384 R, 4–390 T.)

QUANTITY: 1 bulk drum of 5,910 tablets at Huntington, W. Va.

SHIPPED: 10-7-60, from Lafayette, Ind., by Lafayette Pharmacal, Inc.

LABEL IN PART: (Drum) "Control No. 30217 Date 10-5-60 Prepared For Medical Arts Supply Co. Huntington, W. Va. Amount 16,800 White Ct. Caution: * * * Each Tablet represents Ergonovine Maleate 0.2 mgm. 'Warning: * * *' Customer Order No. 60410 Lafayette Pharmacal Inc. Lafayette, Indiana."

RESULTS OF INVESTIGATION: Analysis showed that the article was ergotamine and not ergonovine maleate as labeled. The article was manufactured by C.M. Bundy Co., Cincinnati, Ohio.

LIBELED: 1-10-62, S. Dist. W. Va.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as *ergonovine maleate tablets*, and its strength differed from and its quality and purity fell below the standard set forth in the United States Pharmacopeia, since the article contained ergotamine tartrate and not ergonovine maleate; 501(d)(2)—ergotamine tartrate had been substituted in whole or in part for ergonovine maleate; and 502(a)—the label statement "Ergonovine Maleate" was false and misleading as applied to a product composed of ergotamine tartrate.

DISPOSITION: 3-1-62. Default—destruction.

6940. Imitation drug. (F.D.C. No. 46828. S. No. 27-086 T.)

QUANTITY: 1 btl. of 900 tablets at Omaha, Nebr., in possession of Chris Rexall Drug Store.

SHIPPED: In 1959, from Houston, Tex., by W. L. (Tex) Palmer.

RESULTS OF INVESTIGATION: Examination showed the article to be, in part, a counterfeit of Schering 1000 Meticorten 5 mg. tablets.

LIBELED: 12-1-61, Dist. Nebr.

CHARGE: 501(d)(2)—when shipped, an imitation drug had been substituted, in part, for Schering's Meticorten; 502(a)—while held for sale, the label statement "Schering Meticorten (Prednisone) 5 Mg." was false and misleading as applied to an article consisting, in part, of an imitation; 502(i)(2)—the article was, in part, an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug.

DISPOSITION: 3-8-62. Consent—delivered to the Food and Drug Administration.

6941. Rubber prophylactics. (F.D.C. No. 46872. S. No. 26-154 T.)

QUANTITY: 26 gross cases, 12 ctns. each, containing 4 pkgs. of 3 devices, at Detroit, Mich.

SHIPPED: 4-10-61 and 7-7-61, from Cincinnati, Ohio, by General Sales Co.

LABEL IN PART: (Ctn. and pkg.) "X Cello's Prophylactics A Product of Latex Sold For Prevention of Disease Only Mfd. by The Killian Mfg. Div. of the Akwell Corp. Akron, Ohio."

RESULTS OF INVESTIGATION: Examination showed that 5.77 percent of the article contained holes.

LIBELED: 1-2-62, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statements "Sold For Preven-

tion of Disease Only" were false and misleading as applied to an article containing holes.

DISPOSITION: 2–21–62. Default—destruction.

DRUG FOR VETERINARY USE

6942. Oxytocin injection. (F.D.C. No. 46984. S. No. 28–763 T.)

QUANTITY: 502 10-cc. vials at Des Moines, Iowa.

SHIPPED: 10–13–61, from Madison, Wis., by Forbes Laboratories, Inc.

LABEL IN PART: (Vial) "10 cc. Oxytocin-purified oxytocic principle for parenteral use * * * 20 USP units per CC (double the potency of USP oxytocin injection) see package enclosure for full directions, manufactured for Diamond Laboratories, Des Moines, Iowa, 4633 for veterinary use only."

RESULTS OF INVESTIGATION: Analysis showed that potency of the article was about 50 percent in excess of the declared amount of USP posterior pituitary units per cubic centimeter.

LIBELED: 1–16–62, S. Dist. Iowa.

CHARGE: 501(b)—when shipped, the strength of the article differed from the standard set forth in the United States Pharmacopeia for *oxytocin injection;* and 502(a)—the label statement "20 USP units per CC' was false and misleading as applied to a product the potency of which was about 50 percent in excess of the declared amount.

DISPOSITION: 3–12–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6943. Proten V powder, Proten A powder, and Geriatric liquid. (F.D.C. No. 45535. S. Nos. 39–621/3 R.)

QUANTITY: 71 1-lb. btls. of *Proten A powder*, 107 8-oz. btls. of *Proten V powder*, and 48 1-pt. btls. of *Geriatric liquid*, at St. Louis, Mo.

SHIPPED: Between 5–13–60 and 10–19–60, from Los Angeles, Calif., by William T. Thompson Co.

LABEL IN PART: (Btl.) "Thompson's Proten A High Protein Concentrate * * * Animal-Vegetable Protein Supplement * * * Manufactured by Wm. T. Thompson Co."; Thompson's Proten V High All Vegetable Protein Concentrate * * * All Vegetable Protein Supplement * * * Manufactured by Wm. T. Thompson Co."; and "Thompson's Geriatric Liquid * * * Digestive Enzymes, Lipotropics and B-Complex Vitamins in Liquid Form Wm. T. Thompson Co. * * * Especially formulated for people over 40."

ACCOMPANYING LABELING: Counter display placards entitled "Higher Protein Potency Thompson's Proten" and "Don't Be Old at 40 Be Young at 60"; window banners entitled "Thompson's Proten A High Protein Supplement" and "Stop 'Slow Down' Over 40 Thompson's Geriatric Liquid"; leaflets entitled "Powder and Tablets Containing All the Essential Amino Acids Thompson's Proten"; window display sheets entitled "Thompson's Increased Vitality & Vigor For People Over 40"; pamphlets entitled "Stop 'Over 40' Slow Down Thompson's Geriatric Liquid & Tablets"; and newspaper mats reading in part "Men and Women 40 to 85 Stop That Over 40 Slow Down."

*See also Nos. 6901, 6904, 6908, 6912–6915, 6920–6923, 6925, 6926, 6928–6932, 6934–6941.

LIBELED: 3–31–61, E. Dist. Mo.

CHARGE: *Proten V powder* and *Proten A powder*, 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective to develop athletes for weight reducing and weight control, to supply pep through increased protein intake, restore those mentally and physically fatigued, feel and look better, appease appetite, build healthy bodies, promote growth in children, build new tissue, repair tissues after wasting illness, and supply protein in instances of tissue wastage, anemia, bone atrophy, and edema.

Geriatric liquid, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article provided digestive and nutritional factors to restore and maintain, at high levels, physiological processes which tend to slow down with aging; was a digestive nutritional tonic and a therapeutic "aperitif"; was a "Fountain of Youth" formula; and that the article was adequate and effective as a treatment for and preventive of premature aging, tiredness, sickness, an appearance older than actual, indigestion, poor appetite, fatigue, nervousness, irritability, sleeplessness, low resistance to simple infections, frequent colds, pains and weakness in limbs, bleeding gums, headaches, listlessness, loss of weight, lack of energy, insomnia, dry, itching skin, and "old age slow down"; and to restore ability to keep up with younger people; promote vigor, vitality, and a feeling of general well-being for people over 40; to be youthful appearing, vigorous, and healthy at 70; develop more "get up and go" for tired, rundown people; promote vigorous maturity; restore normal, useful lives, for pep, zest, and energy, and to feel and look one's best.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 6–2–61. Consent—claimed by Wm. T. Thompson Co. and destroyed.

6944. Squaw Paw Liniment and Squaw Paw Herbs. (F.D.C. No. 46580. S. Nos. 27–503/4 T, 34–904 T.)

QUANTITY: 13 cases, 72 ctnd. btls. each, 79 2-oz. btls., and 75 1-oz. btls. of liniment; and 1,152 1-oz. boxes of herbs, at Topeka, Kans.

SHIPPED: Subsequent to 9–1–61, from Des Moines, Iowa, by John C. Vogt.

LABEL IN PART: (Btl. and ctn.) "Squaw Paw Brand Famous Liniment Active Ingredients: Oil Eucalyptus, Turpentine, Oil Mustard (synthetic) Methyl Salicylate, Sassafrasy Fraction of Camphor Oil, Pine Oil, Camphor Oil, and Refined Kerosene. Certified Color * * * Prepared for Squaw Paw Medicine Co., P.O. Box 977 Spokane, Wash." and (box) "Squaw Paw Brand Herbs * * * Prepared For—Address All Mail To Squaw Paw Medicine Company, P.O. Box 977 Spokane 4, Washington."

ACCOMPANYING LABELING: Leaflets entitled "Squaw Paw Brand Famous Liniment," "Squaw Paw Brand Herbs * * * Squaw Paw Medicine Company," and "Scientific Food Chart."

LIBELED: 10–23–61, Dist. Kans.

CHARGE: *Squaw Paw Liniment*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was adequate and effective as a treatment for sprains (unqualified), bruises, frostbite, non-

poisonous insect bite, simple headache, neuralgia, wrenches, children's minor injuries, and toothache.

Squaw Paw Herbs, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that it was adequate and effective as a treatment for biliousness, colds, piles, pain in back, neck, shoulders or hips, heartburn, heart palpitation, biliousness or sick headache, sour or sick stomach, belching, bloating, gas on stomach, rheumatism, lumbago, female complaints, bladder trouble, kidney trouble, asthma, indigestion, colitis, blood disease, various skin diseases, ulcers, liver trouble, and appendicitis.

DISPOSITION: 12–13–61. Default—destruction.

6945. Special dietary foods. (F.D.C. No. 45946. S. Nos. 68–585 R, 68–589 R.)

QUANTITY: 11 250-tablet btls. of *Alliver* and 1 300-tablet btl. of *Pap-Okra*, at Tulsa, Okla.

SHIPPED: 1–27–61, from Santa Rosa, Calif., by Randal Nutritional Laboratories.

LABEL IN PART: (Btl.) "Randal's Alliver Tablets * * * This product contains the finest of Livers from healthy Reindeer * * * Manufactured by Randal Nutritional Products, Santa Rosa, California" and "Randal's Pap-Okra Tablets Contains: Papaya (entire) Cabbage (juice) Okra (entire) Alfalfa (juice) Comfrey (entire) Phytolacca Manufactured by Randal Nutritional Laboratories Santa Rosa, Calif."

LIBELED: 6–13–61; amended libel 8–22–61, N. Dist. Okla.

CHARGE: 502(a)—when shipped (*Alliver tablets*), the label statements "valuable in all cases when a raw liver is indicated" and "retaining enzyme values" were false and misleading; and (*Pap-Okra tablets*), the label contained false and misleading representations that the article was adequate and effective to promote digestion and elimination.

The libel alleged also that certain other products were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 8–23–61, the case was transferred to the Southern District of California. 1–25–62. Default—destruction.

6946. Nutri-Bio food supplements. (F.D.C. No. 46753. S. No. 3–519 T.)

QUANTITY: 99 pkgs. of *vitamin and mineral tablets*, 100 pkgs. of *Protein tablets (meatless)*, 177 pkgs. of *Baby-Bio* 26 pkgs. of *Protein Instant-Mix*, at Washington, D.C., in possession of R. B. Andrews, distributor.

SHIPPED: Between 10–2–61 and 11–8–61, from Elk Grove Village, Ill., Los Angeles and El Segundo, Calif., by Nutri-Bio Corp.

LABEL IN PART: (Pkg.) "Nutri-Bio Vitamin and Mineral Tablets * * * from natural food sources * * * Each Carry-Pak Contains a 7-day adult supply * * * contains 26 Nutri-Paks * * * 364 Vitamin Tablets * * * 728 Mineral Tablets better NUTRItion thru BIOchemistry"; (pkg.) "Nutri-Bio * * * Protein (meatless) Lemon Flavor [or "Chocolate Flavor"] * * * Each Carry-Pak contains 45 protein tablets * * * in Ready-To-Eat Tasty Concentrated Tablets * * * 1080 Tablets"; (pkg.) "Nutri-Bio * * * baby-bio natural or organic Vitamins–Minerals–Proteins * * * 60 five gram Baby-Paks 300 grams net wt. * * * Each 'Baby-Pak' contains a one-day supply * * * This package contains 60 'Baby-Paks'"; and (pkg.) "Nutri-Bio * * * Protein ready-to-use instant mix Vanilla Flavor * * * 1 lb. net wt. [or "3 lb. net wt."]."

ACCOMPANYING LABELING: Nutri-Bio Sales Manuals; Nutri-Bio Program Kits; films and record sets entitled "You and Your Future with Nutri-Bio"; records entitled "Give Yourself a Break," "Special Release, Meet Bob Cummings," "Nutri-Bio Presents: FLASH, The L. Lew Henry Story," and "Special Release, Take Care of You For Me"; books entitled "Stay Young & Vital" by Bob Cummings, "Overfed But Undernourished" 8th Edition, by H. Curtis Wood, Jr., "Let's Eat Right To Keep Fit" by Adelle Davis, "The National Malnutrition" by D. T. Quigley, "Feel Like a Million" by Catharyn Elwood, and "Mirror, Mirror on the Wall" by Gayelord Hauser; booklets entitled "Modern Miracle Men" an article by Rex Beech and "The Organic Revolution in Nutrition"; leaflets entitled "Are We Starving at Full Dinner Tables," "Faulty Diet is Blamed for Youth Delinquency," and "Malnutrition affects 999 out of 1000"; booklets entitled "Capsuled Vitamins when do we need them"; leaflets entitled "Nutri-Bio News, August 1961," "Nutri-Bio News, October 1961," "Southern Association," "For Balanced Nutrition * * * Basic Foods," "A Nutri-Bio Product for Everyone/Do You Know," "The Nutri-Bio Program for Better Living," "Baby-Bio by Nutri-Bio," and "Many of You Have Seen My Movies"; reprints of advertisements "Parents Magazine, October 1960," "Parents Magazine, November 1961," and "Life Magazine May 25, 1959"; booklets entitled "Nutri-Bio Protein Recipes" and "Why a food supplement?"; pamphlets entitled "For More Radiant Living" and "Nutri-Bio Sources"; copies of "Nutri-Bio Questionnaire"; cards "Better Nutrition Through Biochemistry"; sales and recruiting kit; order forms; starting kit and General's Manual; and reprints of "Newsweek July 1961."

LIBELED: 11–24–61, Dist. Columbia.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the articles (*vitamin and mineral tablets* and *Baby-Bio*) were adequate and effective for the treatment and prevention of heart trouble, hardening of the arteries, rheumatism, respiratory infections, impotency, frigidity, nervousness, loss of weight, loss of appetite, anemia, pyorrhea, chronic diarrhea, palpitation of the heart, mental imbalance, senility, premature death, reduced resistance to disease and infection, paralysis, undulant fever, arthritis, eczema, virus infections, lung cancer, kidney diseases, diabetes, high blood pressure, tuberculosis, and lack of normal intelligence, for reducing, to promote health, beauty, radiant living, growth, strength, and athletic ability; to feel young and full of pep; to be calm and vibrant and have a zest for living; to stay young and vital; promote growth; prevent juvenile delinquency; and for other purposes; and that the articles were of significant value for special dietary supplementation or therapeutic use by reason of the presence therein of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, and choline; and (*vitamin and mineral tablets*) alfalfa juice and powder concentrate, potassium, sulfur, chlorine, copper, zinc, manganese, magnesium, montmorillonite, other nutritive factors and trace elements; and (*Baby-Bio*) protein; (both lots) that all ingredients in the articles were essential in human nutrition; that the articles were complete and balanced vitamin and mineral food supplements; that everyone needs food supplements; that the American people are the most undernourished people in the world even though overfed; and that the articles are of special significance for special dietary supplementation or therapeutic use because the ingredients were of natural or organic origin; and (*Protein Instant-Mix* and *Protein (meatless) tablets*)

that the articles were adequate and effective for the treatment and prevention of abnormal blood pressure, constipation, poor digestion, mental deterioration, and to be young and full of pep; promote vim, vitality, vigor, athletic ability, energy, growth, health and well being and long life; to keep muscles, tissues, blood, and organs strong and healthy; to be alert; to attain and maintain normal body weight; for zestful living; and for other purposes; and that malnutrition is nearly universal; that the ordinary diet is deficient in protein; that the minimum daily requirement for protein had been established; that the need for protein is increased by physical activity; and (*Protein (meatless) tablets*) that all ingredients of the article were natural or organic; that the article was practically all protein; and that the article was of significant value for special dietary supplementation and for therapeutic use as a source of protein.

DISPOSITION: 12–27–61. Default—portions of the articles and labeling delivered to the Food and Drug Administration; remainder of the articles delivered to a charitable institution and the remainder of the labeling destroyed.

6947. Alfacon tablets, lecithin granules, and herb tea. (F.D.C. No. 46560. S. Nos. 23–806 T, 23–808/9 T.)

QUANTITY: 2 200-tablet btls. of *Alfacon;* 4 unlabeled ½-lb. bags and 11 unlabeled 1-lb. bags of *lecithin granules;* and 9 ctns., 1 unlabeled 8-oz. bag each of *herb tea*, at Denver, Colo., in possession of Tri-County Organic Cooperative.

SHIPPED: Between 11–23–60 and 6–26–61, from North Kansas City, Mo., Los Angeles, Calif., and Woodside, N.Y.

LABEL IN PART: (Btl.) "200 Tablets 400 Mg. in each tablet Alfacon Natural Organic Concentrated Fresh Alfalfa Juice" and (ctn.) "Seelect Brand Imported Comfrey Root * * * Herb Tea Contains Allantoin Net Weight 8 Oz."

ACCOMPANYING LABELING: Pamphlets entitled "Hope For Arthritic Sufferers" and "Alfalfa Rich in Riboflavin"; leaflets entitled "Lecithin," "A Leaf A Day Keeps Illness Away," "Comfrey The Spinach That Promotes Healing," "Comfrey . . . Healing Qualities," and "Comfrey The Spinach That Promotes Bone Healing."

RESULTS OF INVESTIGATION: The *lecithin granules* were repacked from a bulk lot by the dealer. The pamphlets and leaflets were printed locally on order of the dealer.

LIBELED: 10–10–61, Dist. Colo.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for (*Alfacon tablets*) the treatment and prevention of aching joints, swelling, stiffness, backache, arthritic- and rheumatic-like conditions, hypertropic arthritis, sciatica, rheumatoid arthritis, and fatigue; (*lecithin granules*) the treatment and prevention of arthritis, hardening of the arteries, high blood pressure, rheumatic pains, coronary thrombosis, and to control the cholesterol level of the blood; and (*herb tea*) for the treatment of asthma, insomnia, eczema and other skin troubles, digestive disorders, rheumatic complaints, boils, and varicose ulcers, to promote health, and promote bone healing.

DISPOSITION: 1–3–62. Default—destruction.

6948. Water extract of alfalfa. (F.D.C. No. 46911. S. Nos. 31–217/19 T.)

QUANTITY: 24 1-qt. btls., 56 1-pt. btls., and 45 8-oz. btls., at Los Angeles, Calif.

SHIPPED: Between 7–3–61 and 9–26–61, from American Fork, Utah, by Lucerne Laboratories of Utah.

LABEL IN PART: (Btl.) "Lucerne * * * contains Water Extract of Alfalfa (Medicago Sativa) with water, Citric Acid, Tartaric Acid and Sugar added. * * * Lucerne Laboratories of Utah, 275 East State Road, American Fork, Utah."

ACCOMPANYING LABELING: Leaflets entitled "Lucerne * * * is a concentrated extract of Medicago Sativa (alfalfa)."

LIBELED: 1–16–62, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article, as a concentrated extract of alfalfa, was the richest source of valuable minerals; and that the article was adequate and effective for the treatment and prevention of tiredness, and to promote the proper functioning of the nervous system.

DISPOSITION: 2–9–62. Default—destruction.

6949. Wheat germ. (F.D.C. No. 46844. S. No. 26–982 T.)

QUANTITY: 56 cases, 12 12-oz. jars each, at Toledo, Ohio.

SHIPPED: 12–21–61 and 1–3–62, from Tecumseh, Mich., by Dynamic Kernels Foundation, Inc.

LABEL IN PART: (Jar) "12 Oz. Nt. Wt. Hayden's Wheat Germ Salt Free No Sugar Added * * * Dynamic Kernels Foundation, Inc. Tecumseh, Michigan."

LIBELED: 12–11–61; amended libels, 12–20–61 and 1–10–62, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the label contained false and misleading representations that the article was adequate and effective for the treatment of neuritis and arthritis, and to promote regularity.

DISPOSITION: 2–21–62. Consent—claimed by Dynamic Kernels Foundation, Inc., and relabeled.

6950. Vitamin B complex capsules. (F.D.C. No. 46599. S. No. 9–808 T.)

QUANTITY: 1,000 25-capsule btls., 707 50-capsule btls., and 2,160 sets of 1 100-capsule and 1 25-capsule btl. each, at Rochester, N.Y., in possession of Daw Drug Co., Inc.

SHIPPED: 6–27–61, from Detroit, Mich.

LABEL IN PART: (Btl.) "Biplex New Therapeutic 5 Mcg. B–12 Vitamin B Complex Fortified With Liver, Iron and Vitamin C * * * 1 Capsule per day. Distributed by Biplex Products Co., Buffalo, N.Y."

ACCOMPANYING LABELING: Newspaper tear sheets bearing the advertisement reading in part "Tired? Run Down? Nervous? Bi-Plex B_{12}."

RESULTS OF INVESTIGATION: The article was shipped in bulk to Buffalo, N.Y., and after arrival at Buffalo was repacked by Vitamin Capsule Corp., and then shipped to the dealer.

The newspaper tear sheets were displayed at the dealer's retail stores for the purpose of promoting sales of the article.

LIBELED: 10–24–61, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the label statement "5 Mcg. B–12 Vitamin B Complex Fortified With Liver, Iron and Vitamin C" was false and misleading, since the article also contained other ingredients, and since the liver in the article was not of significant value to fortify the article for special dietary supplementation or for therapeutic purposes; and the labeling, namely, the newspaper tear sheets, contained false and misleading representations that the article was adequate and effective for the treatment of tiredness, rundown condition, and nervousness; to build blood rapidly; and to feel better, stronger, and more alive.

DISPOSITION: 1–30–62. Consent—claimed by Daw Drug Co., Inc., and relabeled.

6951. Multivitamins and mineral tablets. (F.D.C. No. 46757. S. No. 49–381 T.)

QUANTITY: 8,000 tablets in a bulk drum and 7 100-tablet btls., at Oakland, Calif., in possession of Lura-Glo Products, Inc.

SHIPPED: 5–24–60, from Chicago, Ill.

LABEL IN PART: (Btl.) "100 Tablets Johnson's 16-Vitamins-16 with 6-Minerals-6 * * * Directions: One Tablet Daily * * * Distributed by Lura-Glo Products, Inc. 1504–32nd St., Oakland, Cal."

ACCOMPANYING LABELING: Leaflets entitled "Keep Fit–Not Fat."

RESULTS OF INVESTIGATION: The article was repacked by the dealer in the bottles described above, and the dealer printed the leaflets mentioned above.

LIBELED: 12–4–61, N. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of retarded growth, respiratory infections, nervous disorders of all types, colitis, anemia, paralysis, degeneration of sex glands, tuberculosis, cholesterol in the blood, and loss of hair.

DISPOSITION: 1–10–62. Default—destruction.

6952. Deturge. (F.D.C. No. 44179. S. No. 66–834 P.)

QUANTITY: 52 8-oz. cans and 45 14-oz. cans at Los Angeles, Calif.

SHIPPED: 11–2–59, from Tulsa, Okla., by Detergen Co.

LABEL IN PART: (Can) "Deturge For Removing Accumulations of Putrefaction and Mucus from the Gastro-Intestinal Tract. Plantago Ovata Blond Magnesium, Trisilicate * * * Detergen Company, Tulsa, Okla. Directions."

ACCOMPANYING LABELING: 21 placards entitled "Deturge for removing accumulations"; 16 wall charts entitled "Deturge Time Table"; and 269 pamphlets and leaflets entitled "Deturge for Removing Accumulations."

LIBELED: 1–18–60, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the self-treatment of other than occasional constipation; that continued use of the article would maintain good health by keeping the intestinal tract free of toxic accumulations; that use of the article was an adequate and effective treatment for all conditions of the small intestine and colon; that the article was of use for other than the temporary relief of occasional constipation; and that the article had other than simple laxative properties.

DISPOSITION: On 3–30–60, pursuant to stipulation by the Government and by the claimant, Detergen Co., an order was entered directing the removal of the case to the Northern District of Oklahoma. Thereafter, interrogatories were served upon the claimant and subsequently answered.

On 5–5–61, the claimant having consented to a decree, judgment of condemnation was entered and the article was ordered released under bond to be brought into compliance with the law. On 1–15–62, the claimant having failed to post bond, an order for destruction of the article was entered.

6953. Red Rooster pills. (F.D.C. No. 46751. S. No. 42–883 T.)

QUANTITY: 26,400 tablets in a labeled bulk drum, 24,000 tablets in an unlabeled bulk drum, and 30 50-tablet btls., at Wyoming, Pa., in possession of Sanapac Co.

SHIPPED: 8–18–61, from Brooklyn, N.Y., by Manhattan Drug Co.

LABEL IN PART: (Drum) "S.F. 5073 Lot #4326 T Harmen Tablets Each tablet contains: * * * Ferrous Gluconate 100 mg. * * * Po. Ext. Passion Flower 100 mg. Po. Damiana 2 mg. Po. Nux Vomica 2 mg. * * * As a Hematinic and Bitter Tonic For Use in Iron Deficiency (Dietary) Anemias * * * Distributed by Manhattan Drug, Brooklyn 3, N.Y." and (btl.) "Sanapac's Red Rooster Pills 50 * * * Stimulant and Tonic A Dietary Supplement * * * Distributor The Sanapac Company, Wyoming, Penna. Formula * * * For Men and Women Only."

ACCOMPANYING LABELING: Window streamers reading in part "Red Rooster Pills give you that get up and go!"

RESULTS OF INVESTIGATION: The bottles described above were repacked by the dealer from bulk stock as described above.

LIBELED: 12–1–61, M. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a stimulant and tonic; to get up and go; and as a hematinic and bitter tonic for use in iron-deficiency anemia.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–9–62. Default—destruction.

6954. Mineral bath. (F.D.C. No. 46604. S. No. 28–689 T.)

QUANTITY: 4 cases, 12 pkgs. each, at Kansas City, Mo.

SHIPPED: 4–13–61, from El Monte, Calif., by Oasis Co.

LABEL IN PART: (Pkg.) "New Hot Springs Mineral Way In Your Own Home Oasis Home Mineral Baths * * * Contain: Sodium Chloride, Sodium Sulphate, Aluminum Sulphate, Magnesium Sulphate, Sodium Tetraborate, Ammonium Aluminum Sulphate * * * Manufactured & Distributed by Oasis Co., El Monte, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Oasis Home Mineral Baths" and display cards reading in part "Oasis Home Mineral Baths For External Use Only."

RESULTS OF INVESTIGATION: Examination showed the article to be in the form of crystals containing salts of sodium, aluminum, magnesium, and ammonia.

LIBELED: 10–26–61, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article would be effective, because of its mineral salt composition, as a treatment for relieving discomfort and pains of arthritis and rheumatism, relieving nervous tension, improving blood circulation, and that use of the article provides all the health benefits obtainable at health resorts.

DISPOSITION: 1–3–62. Default—destruction.

6955. Fountain-Facial with "Keroxylite." (F.D.C. No. 46768. S. No. 3–802 T.)

QUANTITY: 18,000 pkgs., 6 packets each, at Baltimore, Md.

SHIPPED: Between 4–14–61 and 5–5–61, from Wilmington, Del., by Packaging Services, Inc.

LABEL IN PART: (Pkg. and packet) "Six 9-gram Packets Fountain-Facial with 'Keroxylite' Skin Brightener, Cleanser, Antiseptic Each packet contains monopersulfate compound (Ozone*) sodium bicarbonate Alkyl-dimethyl-benzyl ammonium chloride * * * E. I. Du Pont De Nemours & Co., Inc. * * * Medically approved for cleansing and purifying the skin, and for treatment of acne, pimples, blackheads, inflamed hair follicles, and for inhibiting and removal of blemish-causing bacteria Directions * * * Hopkins Chemicals, Inc., Baltimore 2, Maryland."

ACCOMPANYING LABELING: Leaflet entitled "Fountain Facial with 'Keroxylite.'"

LIBELED: 12–5–61, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, bacterial infections of the skin, and inflamed hair follicles.

DISPOSITION: 1–23–62. Default—destruction.

6956. Eterna 27 face cream. (F.D.C. No. 46629. S. Nos. 31–183/6 T.)

QUANTITY: 474 2-oz. jars at Riverside, Calif.; 435 2-oz. jars, 734 4-oz. jars, and 33 8-oz. jars, at San Bernardino, Calif.; and 419 2-oz. jars, 7 4-oz. jars, and 1 8-oz. jar, at Redlands, Calif., in possession of Sage's Complete Markets.

SHIPPED: Between 9–7–61 and 9–29–61, from Passaic, Metuchen, and Edison, N.J.

LABEL IN PART: (Jar) "'Eterna 27' Cream with Progenitin * * * Registered Trademark for Pregnenolone Acetate."

ACCOMPANYING LABELING: Newspaper advertisement in "San Bernardino Sun Telegram" and Riverside "Press Enterprise" both dated 10–15–61; leaflet "Eterna 27" reprint of an article in "Magazine of Wall Street and Business Analysts"; and counter display cards reading "This item [or "Product"] carries the Federal Pure Food and Drug Administration Seal of Approval Wash., D.C."

RESULTS OF INVESTIGATION: The accompanying labeling was prepared by the dealer and printed locally.

LIBELED: 11–14–61, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article had been approved by the Food and Drug Administration.

DISPOSITION: 1–10–62. Consent—claimed by Sage's Complete Markets and relabeled.

6957. Abunda Beauty device. (F.D.C. No. 45937. S. No. 67-398 R.)

QUANTITY: 5 individually ctnd. devices at Lubbock, Tex.

SHIPPED: During July and August 1960, from San Mateo, Calif., by Abunda Products.

LABEL IN PART: (Ctn.) "Abunda Beauty by Abunda Products 20 Forty First Avenue–San Mateo, California" and (carrying case) "Abunda Beauty."

ACCOMPANYING LABELING: Booklets entitled "Abunda Beauty . . . a lovelier you"; leaflets entitled "Abunda Hydro Massage Bosom Beauty" and "Abunda Beauty * * * A New World of Loveliness"; and a number of carrying cases.

RESULTS OF INVESTIGATION: Photographs and labeling indicated the article to be a plastic cup-shaped device with a water hose attachment. In use, the cup was intended to be placed over the female breast with the hose attachment connected to the household water service. The water was caused to be diffused or "swirled" in passing through a perforated disc in the cup base. The swirling water within the cup reportedly served to massage the bust.

LIBELED: 7–5–61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the name of the article "Abunda Beauty," and its labeling contained false and misleading representations that the article was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; and for providing an abundant bust through hydrotherapy.

DISPOSITION: 11–17–61. Default—destruction.

6958. Magnetic bracelets. (F.D.C. No. 46525. S. No. 19–216 T.)

QUANTITY: 311 bracelets at Brownsville, Tex.

SHIPPED: 8–25–61 and 9–6–61, from New York, N.Y., by Patricia Watch Band Co.

LABEL IN PART: "Made in Japan Super Health."

RESULTS OF INVESTIGATION: Examination showed the article to be an aluminum expansion wristband fitted with a magnetic aid, having a gold top and stainless steel back.

LIBELED: On or about 11–8–61, S. Dist. Tex.

CHARGE: 502(a)—when shipped, the label statement "Super Health" was false and misleading since it suggested and implied that the article was adequate and effective for therapeutic uses whereas the article was of no value for any therapeutic use; and 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 12–22–61 and 1–2–62. Default—50 bracelets delivered to the Food and Drug Administration and the remainder destroyed.

6959. Oxygen inhaler. (F.D.C. No. 46927. S. No. 39–087 T.)

QUANTITY: 61 ctns., 24 retail boxes each; 6 ctns.; 15 boxes, 10 cylinders each; and 300 cylinder holders, at New York, N.Y., in possession of Val-U-Air Products, Inc.

SHIPPED: Between 8–9–61 and 11–9–61, from Bloomfield and West Paterson, N.J.

LABEL IN PART: (Retail box) "Oxygen Air-Aid Inhaler & Cartridge Breathe oxygen to relieve: * * * cartridge contains approx. 3 qts. oxygen U.S.P. * * *

Val-U-Air Products Inc. New York, N.Y." and (cylinder and holder) "Caution: Keep Away from oil and heat."

ACCOMPANYING LABELING: Leaflets entitled "Val-U-Air Products Inc. * * * Important–Read Before Using"; instruction inserts for retail box; catalog sheets entitled "Brand new way to give profits a lift"; advertising throw sheets entitled "Air-Aid"; and sales letters reading in part "We are now preparing to launch upon the public an avalanche of advertising . . ." and "The ideal mail order item . . ."

RESULTS OF INVESTIGATION: The article was assembled by the dealer from parts shipped in bulk lots on the above dates. Examination showed the device to be a small cylinder-shaped inhaler designed to hold a replaceable oxygen cartridge. The cartridge contained about 3 liters of compressed oxygen which was released on a metered control. The weight of this pocket-sized unit was about 4½ ounces.

LIBELED: 1–22–62, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving athletic exhaustion, swimming distress, overindulgence, strain, breathlessness, smoke nausea, morning indisposition, headaches, asthma, croup, coronary discomfort, anginal pains, driver fatigue, and respiratory difficulties.

DISPOSITION: 2–28–62. Consent—claimed by Val-U-Air Products, Inc., and released under bond for relabeling.

6960. Bauer vaporizer lamp. (F.D.C. No. 45756. S. No. 70–029 R.)

QUANTITY: 4,239 unlabeled vaporizer lamps, 1 drum of vaporizer liquid, and 5,990 1-oz. aluminum containers of vaporizer liquid designated as "caps," at East Granby, Conn., in possession of Bauer Chemical Co., Inc.

SHIPPED: 2–26–60 and 3–3–60, from New York, N.Y.

ACCOMPANYING LABELING: Leaflets entitled "Now Nasal Congestion Due to Common Colds."

RESULTS OF INVESTIGATION: The article in the aluminum containers was repacked by the dealer from the bulk drum shipped as described above. Examination showed the article to be an electric cone-shaped vaporizer. Vapor was reportedly produced by heating the aluminum cap containing the vaporizer liquid with an electric light bulb. The vaporizer liquid in the drum and in the caps had an odor of camphor, menthol, and eucalyptol. The aluminum cap was disposable after evaporation of the vaporizer liquid.

The leaflets were printed locally and were used in promoting sales of the article.

LIBELED: 5–9–61, Dist. Conn.

CHARGE: 502(a)—while held for sale, the labeling of the article of drug and device contained false and misleading representations that the article was an adequate and effective treatment for clearing nasal congestion due to sinus, postnasal drip, stuffy asthma and bronchitis, and for liquifying mucus; 502(b)

(2)—the drug component of the article failed to bear a label containing an accurate statement of the quantity of the contents; and 502(e)(2)—the label of the drug component of the article failed to bear the common or usual name of each active ingredient contained therein.

DISPOSITION: 12–20–61. Consent—claimed by Bauer Chemical Co., Inc., and relabeled.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6901 TO 6960

PRODUCTS

[1] (6932) Seizure contested.
[2] (6933) Seizure contested. Injunction issued.
[3] (6919) Seizure contested. Contains order of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6932) Seizure contested.
[2] (6933) Seizure contested. Injunction issued.

[2] (6933) Seizure contested. Injunction issued.

[3] (6919) Seizure contested. Contains order of the court.

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U.S. GOVERNMENT PRINTING OFFICE: 1963

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6961–7000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *February 27, 1963.*

CONTENTS

673499—63

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6961. (F.D.C. No. 45254. S. No. 24–258 R.)

INFORMATION FILED: 2–16–61, Dist. Kans., against **John Richard Sallee.**

CHARGE: On 1–25–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–8–61. Imprisonment for 1 year to run consecutively to the sentence which the defendant was then serving in the Missouri State Penitentiary. See also notices of judgment on drugs and devices, No. 6911 (F.D.C. No. 45558).

6962. (F.D.C. No. 46392. S. Nos. 3–521/7 R.)

INFORMATION FILED: 12–7–61, S. Dist. W. Va., against **Bertha C. Coffman, t/a B & E Grill, Lewisburg, W. Va.**

CHARGE: Between 9–8–60 and 10–20–60, *amphetamine sulfate tablets* were dispensed 7 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–8–62. $2,100 fine and 5 years probation.

6963. (F.D.C. No. 47311. S. No. 4–580/2 R.)

INFORMATION FILED: 7–16–62, E. Dist. N.C., against **Phillip Leroy Twiddy (formerly t/a Shell Truck Stop Restaurant, Elizabeth City, N.C.).**

CHARGE: Between 5–23–61 and 5–25–61, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 8–16–62. Sentence of 27 months in prison to commence on the defendant's release from State prison.

6964. (F.D.C. No. 46397. S. Nos. 24–241/2 R, 24–246 R.)

INFORMATION FILED: 12–8–61, E. Dist. Okla., against **Dale Burch, Savanna, Okla.**

CHARGE: Between 11–15–60 and 11–30–60, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4–24–62. $100 fine on each of 2 counts; payment of the fine as to count 2 was suspended.

6965. (F.D.C. No. 46666. S. No. 49–911 R.)

INFORMATION FILED: 1–3–62, Dist. N. Mex., against **James W. Adam (employee of a truck stop), Las Cruces, N. Mex.**

CHARGE: On 12–15–60, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: On 3–19–62, the case was transferred to the W. Dist. Okla. On 4–13–62, the court placed the defendant on 2 years probation.

6966. (F.D.C. No. 42496. S. Nos. 3–253 P, 3–256/7 P, 44–863 P, 87–304 P.)

INFORMATION FILED: 7–19–60, M. Dist. N.C., against **Leon Benjamin Staley (a service station employee), Winston-Salem, N.C.**

CHARGE: Between 11–3–59 and 11–16–59, *amphetamine sulfate tablets* were dispensed 4 times and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–6–61. Sentence of 2 years in prison suspended; probation for 5 years.

6967. (F.D.C. No. 44948. S. Nos. 72–329 P, 87–334/6 P.)

INFORMATION FILED: 3–1–61, E. Dist. S.C., against **Robert Lee Clure, Mildred A. Clure, Greensboro, Ga., formerly of Homestead, Fla., and Cecil Gainey, Society Hill, S.C.**

CHARGE: Prior to 12–3–59 and continuing to 12–11–59, the defendants conspired (count 1) to violate the Federal Food, Drug, and Cosmetic Act with respect to misbranding *amphetamine tablets* by unlawfully dispensing such drugs, contrary to 503(b)(1), after shipment from outside the State of South Carolina.

It was a further part of the conspiracy that Robert and Mildred Clure, would and did obtain from various suppliers, *amphetamine tablets* which had been manufactured outside the State of South Carolina; that Robert and Mildred Clure would and did supply to Gainey *amphetamine tablets* which had been shipped in interstate commerce; that Robert and Mildred Clure would refer to Gainey, prospective customers to whom *amphetamine tablets* would be dispensed without prescription; and that the defendants would and did sell *amphetamine tablets* to customers without prescriptions, contrary to 503(b)(1).

In furtherance, and to effect the objects of the conspiracy, the defendants did within the States of North Carolina and South Carolina commit various overt acts, among others the following:

(1) On 12–3–59, the defendants had a conversation with a Food and Drug Administration inspector regarding the purchase of *amphetamine tablets;*

(2) On 12–11–59, Gainey unlawfully dispensed *tablets containing a mixture of amphetamine sulfate and phenobarbital,* without a prescription;

(3) On 12–11–59, Gainey unlawfully dispensed *dextro-amphetamine sulfate tablets* without a prescription;

(4) On 12–11–59, Gainey unlawfully dispensed *desoxyephedrine hydrochloride tablets* without a prescription.

In addition to the charge of conspiracy, on 12-11-59, the information alleged that *tablets containing a mixture of amphetamine sulfate and phenobarbital* (count 2) were dispensed twice and *amphetamine sulfate tablets* (count 3) and *desoxyephedrine hydrochloride tablets* (count 4) were each dispensed once without a prescription.

PLEA: Guilty by Robert and Mildred Clure to all counts and by Gainey to 2 counts.

DISPOSITION: 12–4–61. Robert Clure—$5,000 fine, 5 years imprisonment suspended, and 5 years probation on condition that defendant have no connections with the truck stop business; Mildred Clure—$5,000 fine, 5 years imprisonment suspended, and 5 years probation; Gainey—$2,000 fine, and 2 years imprisonment. On payment of $500 of the fine, the sentence was suspended, and the defendant placed on probation for 5 years.

6968. (F.D.C. No. 44946. S. No. 72–321 P.)

INFORMATION FILED: 3–1–61, M. Dist. N.C., against **Robert Lee Clure and Mildred A. Clure, Greensboro, Ga., formerly of Homestead, Fla.**

CHARGE: On 11–3–59, *amphetamine sulfate tablets* were dispensed once without a prescription at a service station near Concord, N.C.

PLEA: Guilty by each defendant.

DISPOSITION: 2–5–62. Robert Clure—imprisonment for 1 year; Mildred Clure—$1,000 fine, imprisonment for 1 year suspended, probation for 5 years.

6969. (F.D.C. No. 45568. S. Nos. 65–461/73 R.)

INFORMATION FILED: 3–23–61, E. Dist. N.C., against **DeWitt Clinton Bowman, t/a Carolina Drug Associates, Salemburg, N.C.**

CHARGE: On 2–14–61 and 2–17–61, a total of 7,000 *dextro-amphetamine sulfate capsules*, 8,000 *dextro-amphetamine sulfate with amobarbital capsules*, 10,000 *amphetamine sulfate with dextro-amphetamine sulfate tablets*, 4,000 *dextro-amphetamine sulfate tablets*, 12,000 *amphetamine sulfate tablets*, and 10,000 *amphetamine hydrochloride with phenobarbital tablets*, were dispensed without a prescription.

PLEA: Guilty.

DISPOSITION: 9–21–61. $1,000 fine and 30 months imprisonment.

6970. (F.D.C. No. 46386. S. Nos. 3–738/9 R, 3–740 R, 3–742 R, 3–744/6 R.)

INFORMATION FILED: 11–24–61, E. Dist. Va., against **William H. Zissett, of Columbia, S.C.**

CHARGE: Between 7–17–60 and 7–29–60, at Woodbridge, Va., *dextro-amphetamine sulfate tablets* were dispensed 3 times, *amphetamine hydrochloride tablets* were dispensed twice, and *amphetamine sulfate tablets containing amphetamine hydrochloride and phenobarbital* were each dispensed once, without prescription.

PLEA: Guilty.

DISPOSITION: 2–19–62. The case having been transferred to the U.S. District Court, E. Dist. S.C., for the entry of the plea, the court fined the defendant $200, imposed a sentence of 2 years in jail, which sentence was suspended, and placed the defendant on probation for 4 years.

6971. (F.D.C. No. 46673. S. Nos. 13–703 R, 13–707 R.)

INFORMATION FILED: 2–21–62, N. Dist. Ill., against **Harvey Drugs, Inc., t/a Harvey Rexall Drugs, Chicago, Ill., and Harvey J. Swarttz (president and pharmacist).**

CHARGE: Between 1–27–61 and 5–5–61, *dextro-amphetamine sulfate capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 4–16–62. Corporation—$500 fine, plus costs; Swarttz—$500 fine.

6972. (F.D.C. No. 46401. S. Nos. 30–548/9 R.)

INFORMATION FILED: 2–7–62, M. Dist. Ala., against **Yancey Park Drug Co., Inc., t/a D & D Drug, Montgomery, Ala.**

CHARGE: Between 6–20–60 and 6–21–60, *Dexedrine Sulfate tablets* and *meprobamate tablets* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: **Guilty.**

DISPOSITION: **2–21–62. $500 fine.**

6973. (F.D.C. No. 45548. S. Nos. 29–223/5 R, 29–227 R, 30–174/6 R.)

INFORMATION FILED: 6–8–61, Dist. Minn., against **Walgreen Co. (a corporation), Raymond E. Braun (pharmacist and manager), Joseph F. Magiera, and Robert E. Landes (pharmacists), Minneapolis, Minn.**

CHARGE: Between 5–7–60 and 6–17–60, *Dexedrine Spansule capsules* were dispensed 4 times and *Dexedrine Sulfate tablets* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came to trial on 12–15–61 before the court without a jury. Written briefs were later submitted and oral argument on the briefs was presented on 1–30–62. The court found all defendants not guilty and filed findings of fact and conclusions of law to that effect on 3–6–62.

6974. (F.D.C. No. 46647. S. No. 44–641 R.)

INFORMATION FILED: 12–26–61, W. Dist. Wash., against **Robert Scott Marshall, t/a Drive-In Pharmacy, Port Angeles, Wash.**

CHARGE: On 9–26–60, *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–28–62. $1,000 fine and probation for 2 years.

6975. (F.D.C. No. 46719. S. Nos. 44–963 R, 44–965 R.)

INFORMATION FILED: 4–10–62, W. Dist. Wash., against **Lincoln Pharmacy, Inc., Seattle, Wash., Ray R. Stroble (pharmacist and president), and G. Richard Kerr (pharmacist and vice president).**

CHARGE: Between 9–8–60 and 10–3–60, *Dexedrine Sulfate tablets* were dispensed twice upon requests for refills without authorization by the prescriber.

PLEA: Corporation and Kerr—guilty to 1 count; Stroble—guilty to 1 count.

DISPOSITION: 6–4–62. Corporation—$1,000 fine on 1 count of information. Kerr and Stroble—$750 fine each on 1 count.

6976. (F.D.C. No. 46644. S. Nos. 33–985 R, 34–283 R, 34–285/7 R.)

INFORMATION FILED: 1–15–62, S. Dist. N.Y., against **Morris Rosenblatt, t/a World Drugs, New York, N.Y.**

CHARGE: Between 12–28–60 and 12–1–61, *Dexedrine Sulfate tablets* were dispensed three times without a prescription, and *Chloromycetin capsules* and *penicillin tablets* were each dispensed once by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 3–9–62. Imposition of sentence suspended; probation for 1 year.

6977. (F.D.C. No. 46674. S. Nos. 18–482 R, 18–484 R.)

INFORMATION FILED: 4–20–62, Dist. Colo., against **Loyd A. Karr, t/a Witt's Pharmacy, Denver, Colo.**

CHARGE: Between 1–17–61 and 1–30–61, *Doriden tablets* and *Librium Hydrochloride capsules* were each dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–15–62. Imposition of sentence suspended; probation for 2 years.

6978. (F.D.C. No. 46687. S. Nos. 46–783/4 R, 46–786/92 R.)

INFORMATION FILED: 6–13–62, N. Dist. Ind., against **Brink & Erb, Inc., and Carl L. Brink (president), Fort Wayne, Ind.**

CHARGE: Between 10–18–60 and 11–15–60, *Pentids tablets* were dispensed 3 times, *Nembutal Sodium* capsules and *Equanil tablets* were each dispensed twice, and *Dexedrine Spansule capsules* and *Compazine tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7–5–62. Corporation—$900 fine, plus costs; Brink—6 months in prison suspended.

6979. (F.D.C. No. 46373. S. Nos. 27–654 R, 29–954 R, 29–956 R.)

INDICTMENT RETURNED: 3–23–62, S. Dist. Iowa, against **Tilford E. Johnson (a partner in the partnership of Johnson & Peasley Drugs), Fairfield, Iowa.**

CHARGE: Between 12–1–60 and 12–8–60, *penicillin tablets* were dispensed once and *Dexedrine Sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4–27–62. $500 fine.

6980. (F.D.C. No. 46722. S. Nos. 68–184/6 R, 68–190/6 R.)

INFORMATION FILED: 7–5–62, N. Dist. Okla., against **Julius H. Wendt, t/a Wendt Drug, Tulsa, Okla., and John W. Owens, Jr.**

CHARGE: Between 2–4–61 and 3–10–61, *penicillin tablets* were dispensed 4 times, *methyltestosterone tablets*, *glutethimide tablets* and *meprobamate tablets* were each dispensed twice upon requests for refills of prescriptions without authorization of the prescriber.

PLEA: Wendt—guilty to all 10 counts. Owens—guilty to 8 counts.

DISPOSITION: 7–18–62. Wendt—$5,000 fine and probation for 2 years. Owens—$400 fine and probation for 2 years.

6981. (F.D.C. No. 47358. S. Nos. 20–511 T, 20–513/6 T, 57–121 T, 57–124/7 T.)

INDICTMENT RETURNED: 4–24–62, E. Dist. Okla., against **Floyd L. Rice, Madill, Okla.**

CHARGE: Between 3–6–62 and 3–28–62, *penicillin tablets* and *oxyphenbutazone tablets* were each dispensed twice, *pentobarbital sodium capsules* and *amphetamine sulfate tablets* were each dispensed once, and *Ipral Calcium tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–22–62. $1,000 fine and sentence of 2 years in jail.

6982. (F.D.C. No. 47102. S. Nos. 32–112 R, 32–114 R, 32–116 R.)

INFORMATION FILED: 4–12–62, N. Dist. Ala., against **James A. Robinson and John H. Robinson (partners of Palace Drug Co., Sylacauga, Ala.), and Fred T. Hebson (pharmacist).**

CHARGE: Between 1–26–61 and 3–17–61, *penicillin tablets* were dispensed twice and *Miltown tablets* were dispensed once without a prescription.

PLEA: James A. Robinson—guilty to 1 count; John H. Robinson—guilty to 1 count; Hebson—guilty to 1 count.

DISPOSITION: 6–11–62. James A. Robinson, John H. Robinson, and Fred T. Hebson—$250 fine each.

6983. (F.D.C. No. 45226. S. Nos. 87–748 P, 1–363 R, 1–379 R, 1–382 R, 1–388 R, 1–396 R.)

INFORMATION FILED: 8–18–61, N. Dist. Ga., against **Charlton Terry Ellis (pharmacist), Brookhaven, Ga.**

CHARGE: Between 2–20–60 and 5–31–60, *Miltown tablets* were dispensed 6 times upon request for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 1–22–62. Probation for 3 years.

6984. (F.D.C. No. 45697. S. Nos. 6–692 R, 6–694/700 R, 6–941/4 R, 6–946/9 R, 7–601 R, 7–603/4 R, 7–606/8 R, 7–610/3 R, 7–615/18 R.)

INFORMATION FILED: 7–7–61, Dist. Mass., against **Star Pharmacy, Inc., Cambridge, Mass., and George Skenderian, Sr. (president).**

CHARGE: Between 3–28–60 and 9–7–60, *Miltown tablets* were dispensed 16 times, *Butazclidin tablets* were dispensed 6 times, and *thyroid tablets* and *Dexedrine Sulfate tablets* were each dispensed 4 times, upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere.

DISPOSITION: On 12–5–61, the case came to trial and evidence was presented. On 12–6–61, the court accepted pleas of nolo contendere and on 1–8–62, the corporation and the individual were each fined $1,000.

6985. (F.D.C. No. 46372. S. Nos. 1–733 R, 3–042 R, 59–096 R, 59–118 R, 59–141 R, 74–953 R.)

INFORMATION FILED: 11–24–61, W. Dist. N.C., against **Daniel C. Lisk, t/a Lisk Prescription Pharmacy, Charlotte, N.C.**

CHARGE: Between 12–5–60 and 4–24–61, *Miltown tablets* were dispensed 4 times and *Seconal Sodium capsules* were dispensed twice, upon requests for refills of prescriptions without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 4–2–62. $750 fine and prayer for judgment continued for 2 years. On 4–9–62, the fine was reduced to $600.

6986. (F.D.C. No. 46711. S. Nos. 2–009 R, 2–014 R, 2–018 R, 2–022 R, 74–162 R, 74–664 R, 74–674 R, 74–682 R.)

INFORMATION FILED: 3–16–62, S. Dist. Fla., against **Salvatore P. Leone, t/a White Cross Pharmacy, Miami, Fla.**

CHARGE: Between 3–17–61 and 5–22–61, *Miltown tablets* were dispensed 8 times upon requests for refills of a prescription without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 6–11–62. $1,000 fine; probation for 2 years.

6987. (F.D.C. No. 46389. S. Nos. 45–999 R, 46–009 R, 46–014 R, 59–063 R, 59–087 R, 59–092 R, 59–097 R, 74–947 R.)

INFORMATION FILED: 12–14–61, W. Dist. N.C., against **Belmont Drug Co., Belmont, N.C. (a partnership), Robert Bruce Bryan, Sr. (partner), Robert Bruce Bryan, Jr. (employee), and John S. LeGette (pharmacist).**

CHARGE: Between 1–30–61 and 4–19–61, *Miltown tablets* and *Equanil tablets* were each dispensed 4 times, by refilling prescriptions without obtaining authorization by the prescriber.

PLEA: Guilty by partnership to all 8 counts of information, by LeGette to 2 counts, and by Bryan, Sr., and Bryan, Jr., to 3 counts each.

DISPOSITION: 4–5–62. $750 fine and prayer for judgment continued for 2 years against defendants, jointly.

6988. (F.D.C. No. 46663. S. Nos. 45–951 R, 45–983 R, 59–083 R, 59–089 R, 59–098/9 R, 59–137/8 R, 59–156 R.)

INFORMATION FILED: 2–9–62, M. Dist. N.C., against **Eastwood Pharmacy, Inc., Harold B. Puntch (manager), and Joe Neal Reese (pharmacist), Kannapolis, N.C.**

CHARGE: Between 2–8–61 and 4–14–61, *Miltown tablets* were dispensed 5 times and *Dexedrine Sulfate tablets* were dispensed twice by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came to trial on 4–17–62, before the court without a jury and was concluded on the same day by a verdict of guilty. The corporation was fined $1,000 and each individual was fined $500.

6989. (F.D.C. No. 46648. S. Nos. 45–652 R, 45–952 R, 45–996 R, 46–008 R, 57–244 R, 57–275 R, 57–284 R, 57–305 R.)

INFORMATION FILED: 12–14–61, W. Dist. N.C., against **Franklin Drug Store (a partnership), Gastonia, N.C., Henry C. Bell and Raymond W. Biggerstaff (partners).**

CHARGE: Between 10–11–60 and 3–31–61, *Seconal Sodium capsules* and *Pentids tablets* were each dispensed 4 times by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 4–3–62. $750 fine.

6990. (F.D.C. No. 41750. S. Nos. 8–429 P, 8–432/3 P, 8–435/7 P, 8–722/6 P, 8–744 P.)

INFORMATION FILED: 7–9–58, W. Dist. N.Y., against **W. C. Dambach, Inc., Buffalo, N.Y., Monroe D. Washburn (secretary-treasurer), Aloysius J. Drasgow (vice president), and Michael A. Lucas (pharmacist).**

CHARGE: Between 2–4–58 and 2–20–58, *Seconal Sodium capsules* were dispensed 6 times (counts 1, 5, 6, 8, 11, and 12), *sulfisoxazole tablets* were dispensed 5 times (counts 2, 3, 4, 7, and 9), upon requests for prescription refills without authorization from the prescriber, and *capsules containing dextro-amphetamine sulfate, vitamins, and minerals* (count 10) were dispensed once without a prescription.

PLEA: Nolo contendere by the corporation to all counts; by Washburn to counts 1, 2, 3, and 7; by Drasgow to counts 4, 6, and 11; and by Lucas to count 12.

DISPOSITION: 12–14–61. Corporation—$2,400 fine, of which $2,000 remitted; Washburn—$800 fine, of which $600 remitted; Drasgow—$150 fine, of which $100 remitted; and Lucas—$50 fine.

6991. (F.D.C. No. 46396. S. Nos. 12–384/6 R.)

INFORMATION FILED: 12–5–61, N. Dist. Ill., against **Charles S. Tracy, t/a Tracy Pharmacy, Chicago, Ill.**

CHARGE: Between 8–31–60 and 9–2–60, *secobarbital sodium capsules* were dispensed once and *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6–19–62. $600 fine, plus costs.

6992. (F.D.C. No. 47313. S. Nos. 63–889/90 R, 63–900 R, 15–221/6 T.)

INFORMATION FILED: 7–23–62, S. Dist. Ohio, against **Albert Delman, t/a Dell Pharmacy, and Charles E. Ormerod (pharmacist), Columbus, Ohio.**

CHARGE: Between 7–26–61 and 10–18–61, *secobarbital sodium capsules* were dispensed 7 times and *pentobarbital sodium capsules* were dispensed twice upon request for a prescription refill without authorization from the prescriber.

PLEA: Guilty by Delman to all counts; by Ormerod to 4 counts.

DISPOSITION: 7–27–62. Delman—fined $200; Ormerod—fined $100.

6993. (F.D.C. No. 45978. S. Nos. 32–915 R, 35–685 R.)

INFORMATION FILED: 8–14–61, Dist. N.J., against **Henry T. Hopkins, t/a Warns Drug Store, Keyport, N.J.**

CHARGE: Between 7–28–60 and 10–20–60, *Seconal Sodium capsules* were dispensed once upon request for a refill of a prescription without authorization by the prescriber and *Butazolidin tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5–8–62. $1,000 fine suspended; probation for 2 years.

6994. (F.D.C. No. 47109. S. Nos. 33–447 T, 33–456 T.)

INFORMATION FILED: 5–22–62, Dist. Minn., against **Desnick Bros. Drug Co., Inc., Josiah J. Desnick (secretary-treasurer), and Stanley H. Maisel (pharmacist), Minneapolis, Minn.**

CHARGE: Between 9–25–61 and 10–15–61, *Benzedrine Sulfate tablets* and *amphetamine sulfate tablets* were each dispensed once without prescription.

PLEA: Guilty by each defendant to one count.

DISPOSITION: 7–20–62. Corporation—fined $700; Desnick—fined $350; Maisel—fined $200.

6995. (F.D.C. No. 47080. S. Nos. 528 T, 1–938/9 T, 1–946/9 T.)

INFORMATION FILED: 5–3–62, N. Dist. Ga., against **Gerald W. Baucom, Atlanta, Ga.**

CHARGE: Between 9–29–61 and 10–24–61, *Biphetamine 20 capsules*, and *pentobarbital sodium capsules* were each dispensed 3 times, and *Biphetamine 12½ capsules* were dispensed once, without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5–17–62. $3,500 fine.

6996. (F.D.C. No. 46006. S. Nos. 30–561/64 R.)

INFORMATION FILED: 8–10–61, N. Dist. Ala., against **James I. Harrison, t/a Central Drug Co., Tuscaloosa, Ala.**

CHARGE: Between 4–28–60 and 5–27–60, *Equanil tablets* were dispensed once and *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–4–61. $500 fine.

6997. (F.D.C. No. 46728. S. Nos. 66–830/2 R, 66–834/7 R.)

INFORMATION FILED: 4–6–62, W. Dist. Okla., against **Raymond J. McGough, t/a Mac's Drug, Oklahoma City, Okla.**

CHARGE: Between 3–21–61 and 4–19–61, *Fiorinal tablets* were dispensed 5 times and *meprobamate tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6–6–62. $250 fine; probation for 3 years.

6998. (F.D.C. No. 46394. S. Nos. 30–843/4 R.)

INFORMATION FILED: 2–5–62, M. Dist. Ala., against **Price Drug Co. (a partnership), Montgomery, Ala.**

CHARGE: On 5–17–60, *meprobamate tablets* and *Dexedrine Sulfate tablets* were each dispensed once, by refilling a prescription without obtaining authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 2–8–62. $1,000 fine.

6999. (F.D.C. No. 45575. S. Nos. 83–742 P, 83–804 P.)

INFORMATION FILED: 10–19–61, W. Dist. Tex., against **Okies Drug Co., Inc., El Paso, Tex.**

CHARGE: Between 9–26–59 and 2–17–60, *meprobamate tablets* and *pencillin tablets* were each dispensed once upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 1–19–62. $200 fine.

7000. (F.D.C. No. 45576. S. Nos. 15–935 R, 15–939 R, 15–940 R.)

INFORMATION FILED: 11–13–61, E. Dist. Tenn., against **Jack E. Johnson, t/a Washington Pike Pharmacy, Knoxville, Tenn.**

CHARGE: Between 8–16–60 and 8–25–60, *methyltestosterone tablets* were dispensed twice and *glucosamine-oxytetracycline capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–13–62. $300 fine.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6961 TO 7000

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6973, 6988) Prosecution contested.

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D.D.N.J., F.D.C. 7001–7060 Issued April 1963

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7001–7060

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or summary judgment, and including, in one case, the entry of a decree of injunction; (2) criminal proceedings which were terminated upon pleas of nolo contendere or guilty; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *April 12, 1963.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 7007, 7009, 7011, 7023, 7030, 7047; an imitation of, and sale under name of, another drug, see No. 7042; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7007, 7030; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7007–7009, 7011, 7029, 7030; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 7023; cosmetics, actionable under the drug provisions of the Act, Nos. 7054, 7055.

678106—63——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 7001–7060

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its quality or purity fell below the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(l), the article was composed wholly or in part of a kind of penicillin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7001. Pre-Creatine capsules, Neo-Creatine capsules, Neo-Creatine granules, and Vi-Arthra-M capsules. (Inj. No. 419.)

COMPLAINT FOR INJUNCTION FILED: 10–13–61, N. Dist. Calif., against Andrew Doty, San Francisco, Calif.

CHARGE: The complaint alleged that the defendant was engaged in the business of promoting the interstate sale and distribution of the following drugs: *Pre-Creatine capsules*, *Neo-Creatine capsules*, *Neo-Creatine granules*, and *Vi-Arthra-M capsules;* that the *Pre-Creatine capsules*, *Neo-Creatine capsules*, and *Neo-Creatine granules* were offered for increasing available energy to muscles

and nerves damaged by heart and neuromuscular diseases; that the *Vi-Arthra-M capsules* were offered for energy restoration in detoxification and for the relief of pain associated with rheumatism and arthritis; that the *Pre-Creatine capsules* contained betaine anhydrous and glycocyamine; that the *Neo-Creatine capsules* and the *Neo-Creatine granules* contained betaine anhydrous and glycine; and that the *Vi-Arthra-M capsules* contained betaine, glycocyamine, glucuronolactone, para-aminobenzoic acid, sodium gentisate, and vitamin C. It was alleged further that all of these drugs were new drugs within the meaning of the law and that they may not be introduced into interstate commerce in the absence of an effective new drug application.

The complaint alleged also, with respect to the *Pre-Creatine capsules*, that the defendant submitted a new drug application in the name of Mercury Pharmaceuticals, Inc.; that, in November 1958, this new drug application became effective; and that, on November 27, 1959, this new drug application was suspended on the ground that it contained a number of untrue statements of material facts.

The complaint alleged further that, with respect to the other drugs, no new drug application was filed or ever became effective; that subsequent to November 27, 1959, the defendant continued to introduce all of these new drugs into interstate commerce without having an effective new drug application with respect to any of them; and that the defendant violated the law by causing the introduction and delivery for introduction into interstate commerce of such new drugs since there was no effective new drug application with respect to any of them.

DISPOSITION: On 10–16–61, a consent decree of permanent injunction was entered, enjoining the defendant from causing to be introduced or delivered for introduction into interstate commerce *Pre-Creatine capsules, Neo-Creatine capsules, Neo-Creatine granules, Vi-Arthra-M capsules* or any similar drug, or any other drug containing betaine anhydrous, glycocyamine, glycine, betaine, glucuronolactone, para-aminobenzoic acid, or sodium gentisate, without having an effective new drug application for such drug.

7002. Pre-Creatine capsules. (F.D.C. No. 45212. S. No. 23–401 R.)

INFORMATION FILED: 6–12–61, N. Dist. Calif., against Andrew Doty, t/a Creatine Laboratories, Inc., San Francisco, Calif.

SHIPPED: 1–19–60, from San Francisco, Calif., to Kansas City, Mo.

LABEL IN PART: (Btl.) "100 Capsules, PRE-CREATINE, Contains Precursors of Creatine Caution Federal Law Prohibits Dispensing without Prescription Manufactured for Creatine Laboratories, Inc., San Francisco."

CHARGE: 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

PLEA: Guilty.

DISPOSITION: 11–6–61. $300 fine and probation for 2 years.

7003. Li-Bex with iron and succinylcholine chloride injection. (F.D.C. No. 47155. S. Nos. 23–357/8 T.)

QUANTITY: 357 vials, each in a plastic case, of *Li-Bex with iron* and 755 vials, each in a plastic case, of *succinylcholine chloride injection*, at Denver, Colo., in possession of Lyle A. Wittney & Co., Inc.

SHIPPED: Between 9–19–61 and 12–14–61, from Decatur and Chicago, Ill.

LABEL IN PART: (Vial and case) "30 cc. * * * Li-Bex With Iron Each 2 cc. Represents Vit. B–12 Activity (From Liver Inj. U.S.P. Beef) Equivalent to: Cyanocobalamin 1.0 mcgm. * * * Caution:" and "10 cc. Vial Succinylcholine Chloride Injection 20 mg. per cc. * * * Warning: For use only by skilled anesthetists with facilities for immediate artificial respiration. Manufactured for Wittney & Co., Inc. Denver, Colorado."

ACCOMPANYING LABELING: Leaflet entitled "Succinylcholine Chloride Injection."

RESULTS OF INVESTIGATION: The leaflets were prepared by the dealer and the labels of *succinylcholine chloride injection* were supplied to the manufacturer by the dealer. The *Li-Bex with iron* was shipped by Medical Chemicals Corp., Chicago, Ill.

LIBELED: 2–21–62, Dist. Colo.

CHARGE: (*Li-Bex with iron*) 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with rspect to the drug; (*succinylcholine chloride injection*) and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was a drug intended for veterinary use which, because of its toxicity or other potentiality for harmful effect, or the method for its use, was not safe for animal use except under the supervision of a licensed veterinarian, and its label failed to bear the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian," and its label also failed to bear the recommended or usual dosage for each animal species for which the article was intended.

DISPOSITION: 4–9–62. Consent—claimed by Lyle A. Wittney & Co., Inc. The *Li-Bex with iron* was destroyed and the *succinylcholine chloride injection* was released under bond for relabeling.

7034. Tain oral suspension and Tain Inlay-Tab tablets. (F.D.C. No. 46967. S. Nos. 27–395/6 T, 28–879/80 T, 29–401/2 T.)

QUANTITY: 131 8-oz. ctnd. btls. and 183 50-tablet ctnd. btls.; 9 cases, 12 50-tablet ctnd. btls. each, and 5 cases, 12 8-oz. ctnd. btls. each; and 14 8-oz. ctnd. btls. and 33 50-tablet ctnd. btls., at Kansas City, Mo.

SHIPPED. Between 12–29–61 and 1–29–62, from Lincoln, Nebr., by Dorsey Laboratories.

LABEL IN PART: (Btl. and ctn.) "8 Fl. Oz. List No. 6050 Dorsey Tain Oral Suspension Caution * * * Dorsey Laboratories a division of the Wander Company, Lincoln, Nebraska * * * Each Teaspoonful (5 ml.) contains: Triacetyloleandomycin 125 mg. Triaminic[R] 25 mg. (phenylpropanolamine hydrochloride) 12.5 mg. pheniramine maleate 6.25 mg. pyrilamine maleate 6.25 mg. Acetaminophen 150 mg. * * * Expiration Date May '63"; (ctn. only) "Triacetyloleandomycin is effective against most gram positive organisms involved in respiratory infections. * * * Has analgesic and antipyretic action * * * is an effective oral nasal decongestant and has antihistaminic action"; and (50-tablet btl. and ctn.) "50 Tablets List No. 1339 Dorsey Tain Antibiotic Decongestant Analgesic Each Tain Inlay-Tab contains: Triacetyloleandomycin equivalent to 125 mg. oleandomycin Triaminic[R] 25 mg. phenylpropanolamine hydrochloride 12.5 mg. pheniramine maleate 6.25 mg. pyrilamine maleate 6.25 mg. Calurin[R] (calcium acetylsalicylate carbamide) (equivalent to aspirin 300 mg.) Caution: * * * Dorsey Laboratories a division of The Wander Company Lincoln, Nebraska Expiration Date Dec. '63."

ACCOMPANYING LABELING: Leaflet entitled "Dorsey Tain[R] Composition" and folder entitled "Time to Take 'Em Out Again."

RESULTS OF INVESTIGATION: New drug applications for these articles were made effective with labeling offering them specifically for the "symptomatic relief of the common cold (malaise, headache, muscular cramps, aches and pains) and the prevention of secondary complications due to susceptible organisms" and with the caution that "if resistant infection or super infection appears discontinue the drug and institute specific therapy or supportive treatment," whereas the article was being recommended and suggested for the treatment of susceptible infections which complicate the common cold, other respiratory infections and other infections.

LIBELED: On or about 2–13–62, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective as a treatment for tonsillitis, pharyngitis, otitis media, bronchitis, pneumonitis, bronchopneumonia, rhinitis, cervical lymphadenitis, coryza, lobar pneumonia, tracheitis or tracheobronchitis, influenza, adenoiditis, bronchial asthma, croup and postnasal infection; that the analgesic ingredient, namely, acetaminophen, was safer in children than salicylates; that the antipyretic effect of the articles did not mask the diagnostic importance of persistent fever; and (*Tain oral suspension*) that it met pediatric requirements in upper respiratory infections; that when side effects occur they were not usually attributable to the article; that the article was an upper respiratory infections antibiotic proved effective in pediatric use; that it was indicated in the treatment of susceptible infections which complicate the common cold, and other respiratory infections; that children did not become drowsy from antihistamines; 502(f)(1)—the labeling failed to bear adequate directions for use and the articles were not exempt from the requirement, since the promotional material for the articles was not the same as, or substantially the same as, the labeling authorized by the new drug applications filed with respect to the articles; and 505(a)—the articles were new drugs, and the new drug applications filed with respect to the articles did not apply to the conditions for which the articles were promoted to the medical profession as set forth in statements contained in the promotional material.

DISPOSITION: 4–24–62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

7005. Streptomycin-procaine penicillin. (F.D.C. No. 47744. S. No. 32–899 T.)

QUANTITY: 448 vials at Los Angeles, Calif.

SHIPPED: During 1960, from New York, N.Y.

LABEL IN PART: "Control: 7G50 10 cc. Streptomycin-Procaine Penicillin Aqueous Suspension Procaine Penicillin 400,000 Units Streptomycin 0.5 Gm. Base per 2 cc."

RESULTS OF INVESTIGATION: Assay showed no significant penicillin potency in the article.

LIBELED: 6–11–62, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(l)—the article was a drug composed in part of penicillin and it was from a batch with respect to which a certificate issued pursuant to 507 had ceased to be effective by reason of its penicillin potency.

DISPOSITION: 7–31–62. Default—destruction.

DRUG FOR VETERINARY USE

7006. Medicated feed. (F.D.C. No. 46754. S. No. 34–802 T.)

QUANTITY: 25 cases, 6 3½-lb. cans each, at Mankato, Minn., in possession of Paul's Products Co.

SHIPPED: 11–23–60, from Indianapolis, Ind.

LABEL IN PART: (Can) "Paul's 3½ Pounds * * * Mycine—4 Water Dispersible Antibiotic Vitamins Each Pound Contains Procaine Penicillin 4 Grams * * * Vitamin K (Menadione Sodium Bisulfite) 120 Mgms. * * * Manufactured by Paul's Products Co. Mankato, Minnesota."

RESULTS OF INVESTIGATION: The article was manufactured in part from raw material (procaine penicillin G), which was shipped on the above date.

LIBELED: 12–29–61, Dist. Minn.

CHARGE: 502(l)—while held for sale, the article contained procaine penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from the requirements of certification.

DISPOSITION: 3–6–62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

7007. Various prescription drugs. (F.D.C. No. 46452. S. Nos. 729/31 T, 734 T, 736/9 T, 741/2 T.)

QUANTITY: 12,426 tablets and capsules, 172 btls. of liquids, and 35 tubes, jars, and cans, at Charleston, S.C., in possession of Prescription Center, Inc.

SHIPPED: On unknown dates, by various drug handlers.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked from physicians' samples into bottles and other containers to which had been affixed labels (in most cases the label originally affixed to the physicians' sample container) bearing the brand names of the drugs, a "complimentary–not for sale" professional sample legend, and the name and address of the manufacturers, packers, or distributors located outside the State of South Carolina; and some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs and bearing labels containing a "complimentary–not for sale" professional sample legend, and the name and address of the manufacturer, packer, or distributor located outside the State of South Carolina.

LIBELED: 9–16–61, E. Dist. S.C.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Sample–Not To Be Sold," "Physician's Sample," "Physician's Package," and similar wording on the labels of some of the articles, were false and misleading as applied to these articles in the possession of a repacker and intended for sale

and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—some of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)—some of the articles were not designated solely by a name recognized in an official compendium and their labels failed to bear (1) the common or usual name of the drug, and (2) the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug, as required by regulations; and 503(b)(4)—some of the articles were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–8–62. Default—destruction.

7008. Various prescription drugs. (F.D.C. No. 46070. S. Nos. 25–137/42 R, 25–144/45 R, 25–147/51 R.)

QUANTITY: 5 cartons of various prescription drugs at Kansas City, Mo., in possession of Prospect Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into bottles having labels bearing brand names indicative of manufacture outside the State of Missouri and bearing the words "Complimentary," "Professional Trial Package," "Professional Sample" or similar wording and the names and addresses of the manufacturers, packers, or distributors located outside the State of Missouri; and of quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, and distributors outside the State of Missouri.

LIBELED: 7–10–61, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the sample legends appearing on the labels affixed to a number of the articles were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles of drug failed to bear a label containing the names and places of business of the manufacturers, packers, or distributors; 502(f)(1)—the labeling of a number of articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to 503(b)(1) and their labels failed to bear an identifying lot number as required by regulations; and 503(b)(4)—a number of the articles were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–16–62. Default—destruction.

7009. Various prescription drugs. (F.D.C. No. 46886. S. Nos. 54–821/2 T, 54–825/7 T, 54–830 T, 54–832/3 T, 54–838/9 T.)

QUANTITY: 13,381 tablets and capsules and 18 btls. of liquids at Daytona Beach, Fla., in possession of Morris Pharmaceuticals.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample" and "Physicians Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida; some labels bearing the words "Professional Sample," "Physician's Sample," or similar wording; and some labels bearing the names and addresses of the manufacturers, packers, or distributors located outside the State of Florida.

LIBELED: 12–28–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Physician's Sample," and similar wording on the labels of a number of the repacked articles of drug, were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the repacked articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the labels of a number of the repacked articles of drug failed to bear the common or usual name of the drugs; 502(e)(2)—the labels of a number of the repacked articles of drug failed to bear the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of a number of the repacked articles of drug failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations; and 503(b)(4)—a number of the repacked articles of drug failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–31–62. Default—destruction.

7010. Various prescription drugs. (F.D.C. No. 46194. S. Nos. 93–113/20 R, 96–759/60 R.)

QUANTITY: 426 assorted containers at Philadelphia, Pa., in possession of Raymon Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into bottles having labels bearing brand names indicative of manufacture outside the State of Pennsylvania, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the words "Professional Sample," "Complimentary," or similar wording, and the names and addresses of manufacturers, packers, or distributors outside the State of Pennsylvania.

LIBELED: 7–27–61, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the sample legends appearing on the labels affixed to a number of the articles were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and

others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement; and 503(b)(4)—a number of the articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2–7–62. Default—destruction.

7011. Proloid tablets. (F.D.C. No. 46740. S. No. 209 T.)

QUANTITY: 5 500-tablet bags at Miami, Fla., in possession of Flamingo Wholesale, Inc.

SHIPPED: Prior to 8–10–61, from Morris Plains, N.J.

LABEL IN PART: (Bag) "Proloid ½ gr. * * * Cost 72041/500 net."

LIBELED: 11–28–61, S. Dist. Fla.

CHARGE: 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the label of the article failed to bear adequate directions for use and the article was not exempt from such requirement since it was a drug subject to 503(b)(1) and its label failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–30–62. Default—destruction.

7012. Hematonic Formula capsules and B complex capsules. (F.D.C. No. 46747. S. Nos. 7–192/3 T.)

QUANTITY: 56 ctnd. btls. of *Hematonic Formula capsules* and 15 ctnd. btls. of *B complex capsules*, at Gloucester, Mass.

SHIPPED: Between 11–17–59 and 6–21–60, from Dallas, Tex.

LABEL IN PART: (Ctn. and btl.) "100 Capsules Hematonic Formula An Anti-Anemia Formula Vitamin B_{12}–B_1, Liver Stomach with Intrinsic Factors and Iron * * * Each capsule contains: * * * Folic Acid 1 Mg." and (ctn. and btl.) "100 Capsules High Potency B Complex With Vitamin B–12, Minerals, Liver, Lipotropes and Intrinsic Factors * * * Each Coated Tablet Contains: * * * Folic Acid 0.5 Mg."

LIBELED: 12–1–61, Dist. Mass.

CHARGE: 503(b)(4)—while held for sale, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–15–62. Default—destruction.

7013. Materfol Elixir. (F.D.C. No. 46461. S. Nos. 39–541/2 T.)

QUANTITY: 23 4-oz. btls. and 27 cases, each containing 12 8-oz. btls., at Santurce, P.R.

SHIPPED: 5–4–60 (27-case lot) and 5–14–61 (23-btl. lot), from Hialeah, Fla., by Delta Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "8 Fl. Oz. [or "4 Fl. Oz."] List 517 Materfol Elixir (Hematinic) * * * Each Teaspoonful (5 CC) Contains: Folic Acid 1 Mg. Liver Extract Equivalent to 2 Grams of Fresh Liver Vitamin B_{12} (From Cobalamin Concentrate) 5 MCG Iron Peptonate 250 MG (44.4 Mg. Iron) Alcohol (By Volume) 10% In a Palatable Vehicle Containing Sorbitol * * * Delta Pharmaceuticals, Inc. Miami – Florida * * * Therapeutic Dose in Anemia: Adults 1 or 2 teaspoonfuls (5 cc) 3 or 4 times a day * * * Children – One half teaspoonful 3 or 4 times a day."

LIBELED: 10–25–61, Dist. P.R.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations and suggestions that the article was adequate and effective for the treatment of all anemias; 503(b)(4)—the article was a drug to which 503(b)(1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1–5–62. Default—destruction.

7014. Viritabs tablets. (F.D.C. No. 46466. S. Nos. 39–550 T, 39–565/66 T.)

QUANTITY: 37 100-tablet btls., 478 50-tablet btls., and 728 6-tablet boxes, at Santurce, P.R.

SHIPPED: Between 9–14–59 and 7–6–61, from Newark, N.J., by Benson Pharmacal Corp.

LABEL IN PART: (100-tablet btl.) "Benson * * * Viritabs * * * Benson Pharmacal Co., Inc., New York 4, N.Y. * * * Each Tablet contains: Testosterone 2 Mgm. * * * Yohimbine Hydrochloride 5 Mgm."; (50-tablet btl.) "Benson * * * Viritabs * * * Benson Pharmacal Co., Inc., New York 4, N.Y. * * * Indicado en casos de impotencia sexual preveniente * * * Cada tableta contiene: Testosterona 2 mgm. * * * Chlorhidrato de yohimbina 5 mgm."; and (box) "Muestras Gratis * * * Benson Viritabs * * * Benson Pharmacal Co., Inc., New York, N.Y. * * * Cada tablets contiene: Testosterona 2 mgm. * * * Clorhidrato de yohimbina 5 mgm."

ACCOMPANYING LABELING: Leaflet in English entitled "Viritabs" and leaflet in Spanish entitled "Viritabs."

RESULTS OF INVESTIGATION: The leaflets were shipped on 7–6–61, to the dealer, by Benson Pharmacal Corp., with the 50-tablet bottles and the 6-tablet boxes.

LIBELED: 10–24–61, Dist. P.R.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of sexual impotence, lack of virility and vigor, weakening of sexual potency, hypogonadism, benign prostatic hypertrophy, and to stimulate energy and rejuvenate youth; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 1–9–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

7015. Frye's remedies. (F.D.C. No. 45924. S. Nos. 79–326 R, 79–329/31 R, 79–333 R, 79–336/9 R.)

QUANTITY: 42 cases, 12 1-pt. btls. each, of *Frye's Laxative Syrup;* 2 cases, 12 1-pt. btls. each, of *Frye's Gentian Iron Tonic;* 17 cases, 12 1-pt. btls. each, of *Frye's Rheumatine Compound No. 50*; 54 100-tablet btls. of *Meditron*; and 12 cases, 12 8-oz. btls. each, of *Frye's Compound Wine of Comfrey*, at Kingsport, Tenn., in possession of Charles T. Frye.

SHIPPED: Between 12–2–59 and 3–30–61, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Frye's Laxative Syrup * * * Prepared for C. T. Frye, 1926 Knoxville Highway P.O. Box 826-Kingsport, Tenn."; "Frye's Gentian Iron Tonic * * * Iron-Gentian Improved with Vitamins B_1 and B_2 Plus Lipotropic Agents and B Complex Factors * * * Distributor C. T. Frye"; "Frye's Rheumatine Compound No. 50 * * * Prepared for C. T. Frye, 1926 Knoxville Highway, P.O. Box 826–Kingsport, Tenn."; "Tablets Hance Meditron"; "Frye's Compound Wine of Comfrey Restorative Wine Bitters * * * Distributor C. T. Frye, P.O. Box 826–Kingsport, Tenn."

LIBELED: 6–9–61, E. Dist. Tenn.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles, namely, the bottle labels, failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Frye's Laxative Syrup*) for the treatment of conditions of the liver; (*Frye's Gentian Iron Tonic*) for the treatment of weakened, rundown conditions, gaining strength, and building up the body; (*Frye's Rheumatine Compound No. 50*) for the treatment of rheumatism and arthritis, and for removing poisons from the blood; (*Meditron*) for the treatment of arthritis and rheumatism; and (*Frye's Compound Wine of Comfrey*) for the treatment of internal bleeding in women; for healing and stopping pains of menstruation; and for irregular menstruation. The articles were offered for such purposes in oral representations made by C. T. Frye.

DISPOSITION: On 7–20–61, Charles T. Frye, claimant, filed an answer denying that the articles were misbranded. Thereafter, on 3–7–62, the claimant having consented to the condemnation of the articles and the entry of an injunction, a decree was entered condemning the articles and permanently enjoining the claimant, his agents, employees, representatives, and all other persons in active concert or participation with him, from holding for sale or causing to be held for sale after shipment in interstate commerce, any of the articles or any similar articles which fail to bear in their labeling: (1) All of the conditions, purposes, and uses for which such articles are intended to be used and for which they are represented, by any means, to the public; and (2) sufficient information to enable the layman to use such articles for such purposes safely, intelligently, and efficaciously, and from doing any act with respect to such articles while held for sale after shipment in interstate commerce, which represents and suggests by means of oral statements that the articles are adequate and effective for diseases and conditions of man. In accordance with the consent decree, the articles were released under bond to be brought into compliance with the law.

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*See also Nos. 7003, 7004, 7007–7011.

7016. Frye's remedies. (F.D.C. No. 46658. S. Nos. 79–326 R, 79–328/31 R, 79–333 R, 79–335/8 R.)

INFORMATION FILED: 2–28–62, W. Dist. Va., against Charles T. Frye, t/a Frye Product Co., Kingsport, Tenn.

ALLEGED VIOLATION: On 4–12–61, while the articles were held for sale at Norton, Va., after shipment in interstate commerce, the defendant caused oral representations to be made holding the articles out as treatments for various diseases, symptoms, and conditions as hereinafter described, which acts resulted in the articles being misbranded.

LABEL IN PART: (Btl.) "One Pint Frye's Laxative Syrup For Moving the Bowels, Assisting and Stimulating the Natural Action Prepared for C. T. Frye 1926 Knoxville Highway, P.O. Box 826 Kingsport, Tenn."; "8 Fluid Ounces Frye's Diuretic & Alkaline For Kidneys and Blood Prepared for C. T. Frye * * * Price $2.00"; "One Pint Frye's Gentian Iron Tonic Distributor C. T. Frye"; "One Pint Frye's Rheumatine Compound No. 50 Prepared for C. T. Frye"; and "100 Tablets * * * Meditron."

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely, (*Frye's Laxative Syrup*) disease conditions of the liver; (diuretic) disease conditions of the prostate gland, bleeding kidneys, and for removing pus from the kidneys, and poisons from the blood; (*Frye's Gentian Iron Tonic*) weakened, rundown conditions and for giving one strength and building one up; (*Frye's Rheumatine Compound No. 50*) for the cure of arthritis and rheumatism; and for removing poisons from the blood; and (*Meditron*) for the cure of arthritis and rheumatism.

PLEA: Nolo contendere.

DISPOSITION: 4–10–62. $1,000 fine.

7017. Amphetamine tablets. (F.D.C. No. 46246. S. No. 84–976 R.)

QUANTITY: 200,000 tablets at De Queen, Ark., in possession of Leroy E. Callahan, M.D.

SHIPPED: On and prior to 8–10–61, from outside the State of Arkansas.

LIBELED: 8–10–61, W. Dist. Ark.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement since it was a prescription drug which would not be used nor dispensed by the practitioner in the course of his professional practice in accordance with 503(b).

DISPOSITION: 9–21–61. Default—destruction.

7018. Amphetamine sulfate tablets. (F.D.C. No. 46280. S. No. 43–301 T.)

QUANTITY: 2 ctns. containing 100,000 tablets at De Queen, Ark., in possession of Leroy E. Callahan, M.D.

SHIPPED: 8–16–61, from Woodside, N.Y.

LIBELED: 8–17–61, W. Dist. Ark.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement since it was a prescription drug which would not be used nor dispensed by the practitioner in the course of his professional practice in accordance with 503(b).

DISPOSITION: 9–21–61. Default—destruction.

7019. Prescription drugs. (F.D.C. No. 46618. S. Nos. 13-143 T, 13-145 T.)

QUANTITY: 12 1,000-tablet btls. of *Gantrisin* and 3 5,000-tablet btls. of *Serpasil* at Chicago, Ill., in possession of G & G Drug Co. (David Greenburg, owner).

SHIPPED: On unknown dates, from Nutley and Summit, N.J.

RESULTS OF INVESTIGATION: The articles had been shipped to an unknown drugstore in the State of Illinois from which the dealer purchased the articles. The articles were intended to be repacked into smaller containers, and were in containers bearing the original labels of their manufacturers. However, the control or lot numbers had been scraped off or otherwise removed from the labels.

LIBELED: 11-2-61, N. Dist. Ill.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear identifying lot or control numbers from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations.

DISPOSITION: 11-27-61. Default—destruction.

7020. Medi-Quick first aid spray. (F.D.C. No. 46448. S. No. 39-226 T.)

QUANTITY: 65 ctns., each containing 12 3-oz. cans, at Brooklyn, N.Y.

SHIPPED: 9-7-61 and 9-28-61, from Bloomfield, N.J., by Lehn & Fink Products Corp.

LABEL IN PART: (Can) "New Instant Medi-Quick first aid spray * * * Contents are under pressure * * * Active Ingredients: Xylocaine *(Astra For Lidocaine) Benzalkonium Chloride, Hexachlorophene, Isapropanol, 7% by volume. Lehn & Fink Prod. Corp. Bloomfield, N.J."

ACCOMPANYING LABELING: Leaflet entitled "Fights infections! Promotes Healing! New Instant Medi-Quick the complete first aid spray"; and display carton, reading in part "New Instant Medi-Quick * * * Stops Pain with Xylocaine Fights Infection even better than iodine!"

LIBELED: 10-25-61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for skin rashes, insect bites, and poison ivy; that it would effectively fight infection and promote healing; and that it was more effective as an antiseptic than tincture of iodine; and 502(f)(2)—the article contained lidocaine (Xylocaine), a local anesthetic, and its labeling failed to bear the warning statement required for local anesthetics, "Caution—Do not use in the eyes. Not for prolonged use. If the conditions for which the preparation is used persists or if a rash or irritation develops, discontinue use and consult physician."

DISPOSITION: 3-22-62. Default—destruction.

7021. Cleer cold tablets. (F.D.C. No. 46892. S. No. 33-818 T.)

QUANTITY: 2 drums containing 190,400 tablets and 117 cases, 12 60-tablet btls. each, at Winona, Minn., in possession of McConnon & Co.

SHIPPED: 3-1-61 and 3-16-61, from Cleveland, Ohio, by Strong Cobb Arner, Inc.

LABEL IN PART: (Drum) "Strong Cobb Arner, Inc., Cleveland, Ohio * * * Manufactured for: McConnon & Co., Winona, Minn. Contents 32800 * * * Special Tablets * * * Formula Contains at time of manufacture: per tablet Pyrilamine Maleate 12.5 mg. Thenylpyramine Hydrochloride 12.5 mg. Aluminum Hydroxide Dried Gel 64.8 mg. Vitamin C (Ascorbic Acid) 25 mg. Scopolamine Aminoxide Hydrobromide 0.25 mg. Phenylephrine Hydrochloride 5 mg. Aspirin 291.6 mg. For the relief of symptoms of colds & hay fever * * * Directions * * * Caution * * * Warning"; (btl.) "Cleer 60 Tablets With Vitamin C."

LIBELED: 1–3–62, Dist. Minn.

CHARGE: 502(f)(2)—when shipped and while held for sale, the labeling failed to bear the required warning statements for articles containing the antihistamines, pyrilamine hydrochloride and thenylpyramine hydrochloride.

DISPOSITION: 3–7–62. Consent—claimed by McConnon & Co. and relabeled.

7022. Soluble calcium capsules. (F.D.C. No. 47609. S. No. 23–360 T.)

QUANTITY: 34 100-capsule labeled btls. and 53 1,000-capsule labeled btls.; 6 cases, 48 100-capsule unlabeled btls. each, and 8 cases, 6 1,000-capsule unlabeled btls. each, at Albuquerque, N. Mex., in possession of Carmel & Co.

SHIPPED: 6–12–61, from St. Louis, Mo., by K–V Pharmacal Co.

LABEL IN PART: (Btl.) "Solu-Cal (Soluable Calcium) For the Treatment of Calcium Deficiency. Each Capsule Contains: 500 mg. (7.7 grains) Calcium Levulinate distributors Carmel & Company * * * Albuquerque, New Mexico" and (case) "#0 Pink Calcium Levulinate Capsules Each Capsule Contains: Calcium Levulinate 0.5 gm. Each capsule supplies 29% of the minimum daily requirement for calcium * * * K–V Pharmacal Company * * * St. Louis, Missouri."

RESULTS OF INVESTIGATION: The individual bottles were labeled by the dealer with the dealer's label.

LIBELED: 5–22–62, Dist. N. Mex.

CHARGE: 502(a)—when shipped, the label statement (case) "Each capsule supplies 29% of the minimum daily requirement for calcium" was false and misleading; while held for sale, the dealer's bottle label contained false and misleading representations that the article was adequate and effective for the treatment of calcium deficiency; and the dealer's bottle label also contained statements comparing the solubility of the article with other calcium compounds, which statements were misleading since the labeling failed to reveal the material fact that the calcium compounds to which the solubility of the article was compared are normally and readily absorbed; and 502(f)(1)—the labeling failed to bear adequate directions for use for the treatment of calcium deficiency, the purpose for which the article was intended.

DISPOSITION: 6–1–62. Consent—claimed by I. C. Carmel, Albuquerque, N. Mex., and released under bond for relabeling.

7023. Medicated lotion. (F.D.C. No. 47374. S. No. 276 T.)

QUANTITY: 234 6-oz. btls. at Oakland Park, Fla.

SHIPPED: 9–27–61, from Winona, Minn., by McConnon & Co.

LABEL IN PART: (Btl.) "6 Fl. Oz. Corsage Medicated Lotion McConnon Quality Products, Winona, Minn."

RESULTS OF INVESTIGATION: Qualitative tests showed that the article contained borates, benzocaine, camphor, and menthol.

The label consisted of printed and graphic matter in a heavy, blue paint-like substance applied to the plastic material of the container. The printed matter was absent in part, causing the name of the article and place of business of the manufacturer to be unreadable. The quantity of contents statement was inconspicuous due to being printed in extremely small type. No directions for use were given on the label.

LIBELED: 3–15–62, S. Dist. Fla.

CHARGE: 502(c)—when shipped, the information required by 502(b) (1) and (2) to appear on the label, namely, the place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents, was not prominently placed thereon with such conspicuousness (as compared with other words and statements in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use; 502(e)(2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; 502(f)(1)—its labeling failed to bear adequate directions for use; and 502(f)(2)—the article contained benzocaine, a local anesthetic, and its label failed to bear a statement warning that the article was not to be used in the eyes; that it was not for prolonged use; and that, if the conditions for which it was used persisted or if rash developed, use of the article should be discontinued and a physician consulted.

DISPOSITION: 4–12–62. Default—destruction.

7024. A-D Caine ointment. (F.D.C. No. 47167. S. No. 26–170 T.)

QUANTITY: 96 ctns., 12 2-oz. tubes each, at East Detroit, Mich.

SHIPPED: 8–30–61, from Cedar Rapids, Iowa, by Pharmich Laboratories.

LABEL IN PART: (Tube) "Phar-Med * * * Lanolized A–D Caine Ointment With Tyrothricin Contains natural Vitamins A and D with Tyrothricin (antibiotic) and 3% Benzocaine (anesthetic) in a special lanolized base, non-greasy. * * * Phar-Med, Inc. Distributors Detroit, Michigan."

LIBELED: 2–27–62, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective for the relief of skin rash (diaper and heat) and skin irritation (windburn, chafing and "detergent hands"), since the article contained a local anesthetic, benzocaine, which, in itself, was capable of producing skin rashes and skin irritation; and 502(f)(2)—the article was labeled as containing the local anesthetic, benzocaine, and the label failed to bear a statement warning against use of the article in the eyes, against prolonged use, and to discontinue use and consult a physician if a skin rash or irritation developed, or the conditions for which the article was used persisted; and, in that it was suggested for use in the relief of hemorrhoids, and the label failed to bear a statement warning that the user should consult a physician in the case of rectal bleeding.

DISPOSITION: 4–16–62. Consent—claimed by Phar-Med, Inc., East Detroit, Mich., and relabeled.

7025. Mineral oil. (F.D.C. No. 47156. S. No. 9–876 T.)

QUANTITY: 2 55-gal. drums, 9 1-gal. btls., 12 ½-gal. btls., 40 1-qt. btls., and 35 1-pt. btls., at Rochester, N.Y., in possession of Rochester Drug Cooperative, Inc.

SHIPPED: On an unknown date, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Extra Heavy Mineral Oil * * * An Intestinal Lubricant * * * Distributed by Rochester Drug Cooperative, Inc. Rochester, N.Y."

RESULTS OF INVESTIGATION: The article in the bottles was repacked by the dealer from bulk drums shipped as described above.

LIBELED: 2–26–62, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the repack label contained false and misleading representations that the article was adequate and effective for the treatment of chronic constipation, intestinal disorders, and piles; and 502(f)(2)—the labeling failed to bear adequate warnings against its misuse, since it failed to bear the warnings that the article should be taken only at bedtime, is not for prolonged use, and should not be administered to infants or young children, in pregnancy, or to bedridden or aged patients unless directed by a physician.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3–27–62. Consent—claimed by Rochester Drug Cooperative, Inc., and relabeled.

7026. Sendol tablets. (F.D.C. No. 46769. S. Nos. 28–217/19 T.)

QUANTITY: 59,760 individually ctnd. 100-tablet btls.; 3,631 individually ctnd. 36-tablet btls.; and 155 display ctns., containing 12 12-tablet boxes each, at Kansas City, Mo., in possession of Dayco Laboratories, Inc.

SHIPPED: On unknown dates between 1958 and 1961, from Cleveland, Ohio.

LABEL IN PART: (Ctn., btl., and box) "Sendol * * * Sendol Company, Distributors, Kansas City, Missouri" and (btl. and box only) "Active Ingredients: Aspirin (Acetylsalicylic Acid), caffeine Alkaloid."

ACCOMPANYING LABELING: Leaflets entitled "You Will Quickly Feel Better With Sendol."

RESULTS OF INVESTIGATION: The article was originally shipped to Sendol Co., Excelsior Springs, Mo., who, in March 1961, sold the name and assets of the company to Dayco Laboratories, Inc.

LIBELED: 12–22–61, W. Dist. Mo.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for quick relief of painful disorders due to simple headaches, colds, pains and aches, and minor aches and pains of rheumatism, neuritis, sciatica, bursitis, and lumbago; and 502(f)(2)—the labeling failed to bear warnings prescribed by regulations for drug preparations containing salicylates, for use in arthritis and rheumatism and for over-the-counter drugs for minor sore throats.

DISPOSITION: 3–28–62. Consent—claimed by Dayco Laboratories, Inc., and released under bond for relabeling.

7027. Abunda Beauty device. (F.D.C. No. 46640. S. No. 23–719 T.)

QUANTITY: 19 cases, each containing 20 individually ctnd. devices, and 4 cases, each containing 23 plastic display units, at Albuquerque, N. Mex.

SHIPPED: 10–17–60, from Menlo Park, Calif., by Pam-Pro Plastics.

LABEL IN PART: (Case) "From: Pam-Pro Plastics 1075 O'Brien Drive Menlo Park, Calif. To: Joseph Ruffino 3109 San Pedro N.E. Albuquerque, New Mexico Qty. 20 Units Weight 32# 18 of 25" and (ctn.) "Abunda Beauty by Abunda Products 20 Forty First Avenue—San Mateo, California."

RESULTS OF INVESTIGATION: Examination showed that the article was a plastic cup-shaped device with a water hose attachment. In use, the cup was intended to be placed over the female breast with the hose attachment connected to the household water service. The water was caused to be diffused or "swirled" in passing through a perforated disc in the cup base and the swirling water within the cup reportedly served to massage the bust.

LIBELED: 12–1–61, Dist. N. Mex.

CHARGE: 502(a)—when shipped, the name of the device "Abunda Beauty" was false and misleading as applied to the device since such name represented and suggested that the device was beneficial to the development of the female breast, whereas, the device was not beneficial to such development; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for use on the female breast.

DISPOSITION: 1–10–62. Default—destruction.

7028. Abunda Beauty device. (F.D.C. No. 46936. S. No. 23–043 T.)

QUANTITY: 98 individually ctnd. devices and 34 plastic display cases at Albuquerque, N. Mex., in possession of James E. Henderson.

SHIPPED: 9–7–60, from Menlo Park, Calif., by Pam-Pro Plastics.

LABEL IN PART: (Ctn.) "Abunda Beauty by Abunda Products 20 Forty-First Avenue, San Mateo, California"; (display case) "Abunda Beauty" (on sides) and "Abunda Beauty 20 Forty-First Ave. San Mateo, Calif." (on lid).

ACCOMPANYING LABELING: Leaflets entitled "Abunda Beauty . . . A Lovelier You" and "Abunda Beauty Basic Concept of Abunda Beauty"; booklets entitled "Abunda Beauty . . . A Lovelier You" and "Abunda Hydro Massage Bosom Beauty."

RESULTS OF INVESTIGATION: Examination showed that the article was a plastic cup-shaped device with a water hose attachment. In use, the cup was intended to be placed over the female breast with the hose attachment connected to the household water service. The water was caused to be diffused or "swirled" in passing through a perforated disc in the cup base and the swirling water within the cup reportedly served to massage the bust.

LIBELED: 1–24–62, Dist. N. Mex.

CHARGE: 502(a)—when shipped and while held for sale, the name "*Abunda Beauty*" and statements appearing in its labeling, contained false and misleading representations that the article was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; and for providing an

abundant bust through hydrotherapy; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for use on the female breast.

DISPOSITION: 2–26–62. Default—20 devices and display cases and accompanying labeling were delivered to the Food and Drug Administration; remainder destroyed.

7029. Affinitizer device. (F.D.C. No. 45524. S. No. 68–735 R.)

QUANTITY: 1 device at Dallas, Tex., in possession of Mrs. Yuba G. Freeman, naturopath.

SHIPPED: Sometime during 1952, from Glendale, Calif.

LABEL IN PART: (Embossed on device) "Affinitizer."

ACCOMPANYING LABELING: Booklet entitled "The Diagnometer Seroyal Brands, Inc., Orinda, California."

RESULTS OF INVESTIGATION: The inspector's photographs and description indicated the article to be in the form of a hollow plastic block, about 12 inches square and 1 inch thick. On the face of the block is an indicator dial with inscribed numbers ranging from 0 to 270. The unit contains no electrical circuit, but the dial operation is reportedly magnetic. Three plastic strings are taped to the plastic block. For diagnostic purposes, one string is held over the area of the patient's heart, one string is placed in the area of the gland or organ to be checked, and one string is held over the dial of the device.

LIBELED: 3–24–62; amended libel 4–26–61, N. Dist. Tex.

CHARGE: 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f)(1)—its labeling failed to bear adequate directions for the purposes for which it was intended, namely, in the treatment of diabetes, and in the diagnosing of the condition of the pituitary, liver, thyroid, and pancreas glands, the purposes for which the article was used by Mrs. Freeman; and 502(a)—when shipped and while held for sale, the labeling accompanying the article, contained false and misleading representations that the article was adequate and effective for diagnosing practically all diseases and conditions including, but not limited to, the following diseases and conditions; pneumonia, tuberculosis, diphtheria, cancer, malaria, syphilis, trichina, meningitis, tapeworm, fibroid tumor, anthrax, kidney stone, gallstone, polio, colitis, tularemia, blood sugar, bronchitis, asthma, rheumatic fever, gastric ulcer, botulism, sinusitis, nephritis, psoriasis, infectious mononucleosis, Vincent's angina, Banti's disease, filariasis, tetanus, hay fever, eczema squamosum, eczema madidans, cirrhosis of the liver, influenza, smallpox, impetigo; and that the article was adequate and effective for (a) determining where spinal adjustments were needed; (b) determining the locations of adhesions in the adbomen; (c) determining whether food contains poison; (d) determining whether the subject's heart and bloodstream are in a normal or subnormal condition; (e) determining the acid-alkaline balance of the body; (f) pointing out the foods which increase vitality in the body and foods which decrease vitality; and (g) pointing out the organs that have succumbed to toxicity and the nature and extent of the disease.

DISPOSITION: Mrs. Yuba G. Freeman filed a plea of intervention and, thereafter, the Government filed interrogatories, which were answered by the intervenor. The Government then filed a motion for summary judgment based on the answers to interrogatories. On 2–24–62, the court entered an order granting the motion for summary judgment, condemning the article, and providing for delivery of the device to the Food and Drug Administration.

DRUG FOR VETERINARY USE

7030. Turkey Formula Streppenmycin. (F.D.C. No. 46156. S. No. 54–595 R.)

QUANTITY: 1 keg containing 18 unlabeled 5-lb. bags at Lone Rock, Wis.

SHIPPED: 5–24–61, from Mankato, Minn., by Paul's Products Co.

LABEL IN PART: (Keg) "Turkey Formula 100 pounds 20/5# bags * * * Streppenmycin * * * As an aid in the control of Streptomycin and Penicillin sensitive bacteria usually present in infectious sinusitis, air sac, or blue comb disease in turkeys. Each pound contains * * * manufactured by Paul's Products Co. Mankato, Minnesota Directions * * * Control No. 213 Exp. Date Sep. 1963."

LIBELED: 8–2–61, W. Dist. Wis.

CHARGE: 502(b)—when shipped and while held for sale, the article failed to bear a label (bag) containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of quantity of contents; 502(e)(2)—its label failed to bear the common or usual name of each active ingredient; and 502(f)(1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 3–17–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7031. Calcium lactate tablets. (F.D.C. No. 47224. S. No. 24–407 T.)

QUANTITY: 4 25,000-tablet drums and 1 20,000-tablet drum at Cleveland, Ohio.

SHIPPED: 12–6–61, from Worcester, Mass.

RESULTS OF INVESTIGATION: Examination showed the presence of moldy tablets.

LIBELED: 3–8–62, N. Dist. Ohio.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as *calcium lactate tablets*, a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality or purity fell below the standard set forth in such compendium by reason of the presence therein of moldy tablets.

DISPOSITION: 4–25–62. Default—destruction.

7032. Trisulfacidin suspension. (F.D.C. No. 47172. S. No. 38–556 T.)

QUANTITY: 8 1-gal, btls. at Birmingham, Ala.

SHIPPED: 11–17–61, from St. Louis, Mo., by Organo Pharmaceutical Co.

LABEL IN PART: (Btl.) "Cyclonized Trisulfacidin Suspension * * * Each Teaspoon (5 cc.) contains: Sulfadiazine 0.166 Gm. Sulfamerazine 0.166 Gm. Sulfamethazine 0.166 Gm. Pyrilamine Maleate 6.25 mg. Pheniramine Male-

*See also No. 7005.

ate 6.25 mg. Phenylpropanolamine HCl 12.5 mg. Sodium Citrate 250 mg. Jamieson-McKames Pharmaceuticals, Inc. St. Louis 16, Mo."

RESULTS OF INVESTIGATION: Analysis showed that the article contained sulfacetamide and not sulfamethazine.

LIBELED: 2–23–62, N. Dist. Ala.

CHARGE: 501(d)(2)—when shipped, sulfacetamide had been substituted in whole or in part for sulfamethazine; and 502(a)—the label statement "Sulfamethazine 0.166 Gm." was false and misleading as applied to a product which did not contain sulfamethazine.

DISPOSITION: 3–26–62. Default—destruction.

7033. Adhesive bandages. (F.D.C. No. 45353. S. Nos. 46–231/33 R.)

QUANTITY: 2 cases, containing 720 individually wrapped bandages in pkgs. of 10 each, and 1 case, containing 720 individually wrapped bandages in pkgs. of 12 each, at Lancaster, S.C.

SHIPPED: 10–6–60, from New Rochelle, N.Y., by Hampton Manufacturing Co.

LABEL IN PART: (Pkg.) "Blue Cross Plastic Adhesive Bangages Sterile * * * Hampton Mfg. Co. New Rochelle, N.Y. Plain Pads"; "Waterproof Blue Cross Sterile Adhesive Bandages Hampton Mfg. Co. New Rochelle, N.Y. * * * 'Mercurochrome' Pads H. W. & D. Brand of Merbromin"; and "Blue Cross Plastic Adhesive Bandages Sterile * * * Hampton Mfg. Co. New Rochelle, N.Y. 'Mercurochrome' Pads H. W. & D. Brand of Merbromin."

LIBELED: On or about 1–30–61, W. Dist. S.C.

CHARGE: 501(b)—the quality and purity of the article, when shipped, fell below the standard for adhesive absorbent bandage (adhesive absorbent compress) set forth in the United States Pharmacopeia since the article was not sterile but was contaminated with living microorganisms; and 502(a)—the label statement "Sterile" was false and misleading.

DISPOSITION: 4–17–62. Default—destruction.

7034. Rubber prophylactics. (F.D.C. No. 47058. S. No. 34–691 T.)

QUANTITY: 15 gross cases of individually foil-wrapped prophylactics, packed in boxes of 3, at St. Paul, Minn.

SHIPPED: 1–8–62 and 2–5–62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Case) "One Gross 3's No. 10 In Foil Peacocks Redi-Wet * * * Dean Rubber Mfg. Co., North Kansas City, Missouri" and (box of 3) "3 Peacocks Redi-Wet Rubbers in Foil * * * An Aid in Preventing Venereal Disease."

RESULTS OF INVESTIGATION: Examination showed 4.74 percent of the article was defective in that it contained holes.

LIBELED: 2–27–62, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 3–13–62. Consent—claimed by Dean Rubber Manufacturing Co. and destroyed.

7035. Rubber prophylactics. (F.D.C. No. 47057. S. No. 34–690 T.)

QUANTITY: 26 cases, 12 ctns. each, containing 12 individually wrapped prophylactics each, at Minneapolis, Minn.

SHIPPED: 1–16–62, from North Kansas City., Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Case) "One Gross Dozens No. 12 In Foil Peacocks Redi-Wet Rubbers * * * Dean Rubber Mfg. Co., North Kansas City, Missouri" and (ctn.) "One Dozen Peacocks Redi-Wet Rubbers in Foil * * * An Aid In Preventing Venereal Diseases."

RESULTS OF INVESTIGATION: Examination showed that 1.62 percent of the article was defective in that it contained holes.

LIBELED: 2–27–62, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Diseases" was false and misleading as applied to an article containing holes.

DISPOSITION: 3–13–62. Consent—claimed by Dean Rubber Manufacturing Co. and destroyed.

7036. Rubber prophylactics. (F.D.C. No. 47219. S. No. 34–575 T.)

QUANTITY: 72 ctns., 12 pkgs. each, containing 12 units each, at St. Paul, Minn.

SHIPPED: Between 8–7–61 and 2–5–62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Pkg.) "One Dozen Peacocks Redi-Wet Rubbers in Foil * * * Dean Rubber Mfg. Co., North Kansas City., Mo. * * * An Aid In Preventing Venereal Disease."

RESULTS OF INVESTIGATION: Examination showed that 2.36 percent of the article was defective in that it contained holes.

LIBELED: 2–28–62, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 3–13–62. Consent—claimed by Dean Rubber Manufacturing Co. and destroyed.

DRUGS FOR VETERINARY USE

7037. Medicated chick starter. (F.D.C. No. 46834. S. No. 23–434 T.)

QUANTITY: 50 50-lb. bags at Eads, Colo.

SHIPPED: Between 3–20–61 and 5–18–61, from Abilene, Kans., by Naturich Mills.

LABEL IN PART: (Bag tag) "Grublets 50 Lbs. Net. Naturich Hi-Energy Chick Starter No. A Medicated * * * Active Ingredients Acetyl-(Para-Nitrophenyl) Sulfanilamide 0.0300 Percent * * * 3-Nitro-4-Hydroxyphenylarsonic Acid 0.0025 Percent * * * Manufactured by Naturich Mills Abilene, Kansas."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 5 percent of the declared amount of 3-Nitro-4-hydroxyphenylarsonic acid.

LIBELED: 12–6–61, Dist. Colo.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "3-Nitro-4-Hydroxyphenylarsonic Acid 0.0025 Percent" was false and misleading.

DISPOSITION: 1-31-62. Default—delivered to a public institution for use as animal feed.

7038. Medicated chick starter premix. (F.D.C. No. 46421. S. No. 85-616 R.)

QUANTITY: 8 100-lb. drums at Caldwell, Kans.

SHIPPED: 5-5-61 and 6-6-61, from Indianapolis, Ind., by Specifide, Inc.

LABEL IN PART: "Specifide Dyna-Ferm CS (Chick Starter Premix); Active Drug Ingredients: Arsanilic Acid 1.98% Procaine Penicillin 0.30 gms/lb; * * * Specifide, Inc. * * * Indpl. Indiana * * * Des Moines, Iowa * * * Mixing Directions * * * Warning."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately .03 gram of procaine penicillin per pound, or 9.7 percent of the declared amount.

LIBELED: 9-15-61, Dist. Kans.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Procaine Penicillin 0.30 gms/lb" was false and misleading as applied to the article which contained less than the declared amount of procaine penicillin.

DISPOSITION: 4-10-62. Consent—claimed by Specifide, Inc., and destroyed.

7039. Medicated feed. (F.D.C. No. 46884. S. No. 35-555 T.)

QUANTITY: 27 5-lb. ctns. at St. Paul, Minn.

SHIPPED: 5-16-60, from Cedar Rapids, Iowa.

LABEL IN PART: "Improved Ovotone No. 20 * * * Active Ingredients: Phenothiazine 45% Powered Tobacco 5%."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 77 percent of the declared amount of phenothiazine.

LIBELED: 1-13-62, Dist. Minn.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess.

DISPOSITION: 3-2-62. Default—destruction.

7040. Medicated feed. (F.D.C. No. 46849. S. No. 15-319 T.)

QUANTITY: 96 100-lb. bags at Louisville, Ky.

SHIPPED: 6-22-61 and 6-29-61, from Reading, Ohio, by Cooperative Mills, Inc.

LABEL IN PART: (Bag) "100 Lbs. Net 49 * * * Cooperative Mills, Inc." and (tag) "Net Weight 100 Lbs. Xtr. Aid Medicated * * * Active Drug Ingredients * * * 3-Nitro-4-Hydroxyphenyl-Arsonic Acid 0.005% Furazolidine 0.005%."

LIBELED: 12-13-61, W. Dist. Ky.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement '3-Nitro-4-Hydroxyphenyl-Arsonic Acid 0.005% Furazolidine 0.005%" was false and misleading as applied to an article containing less than the declared amounts of these ingredients.

DISPOSITION: 2–13–62. Consent—delivered to a public institution for use as animal feed.

7041. **Medicated swine concentrate.** (F.D.C. No. 46802. S. No. 28–215 T.)

QUANTITY: 42 3½-lb. cans at Abilene, Kans.

SHIPPED: On or about June 1960, from Des Moines, Iowa.

LABEL IN PART: "Medicated Swine Concentrate Dihydrostreptomycin-Penicillin-Vitamins * * * Dihydrostreptomycin base (as sulfate) 3 grams per pound."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of dihydrostreptomycin.

LIBELED: 12–22–61, Dist. Kans.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess.

DISPOSITION: 2–7–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7042. **Imitation drugs.** (F.D.C. No. 46376. S. Nos. 1–549/55 T.)

INFORMATION FILED: 9–1–61, N. Dist. Ga., against McKinney's Apothecary, a partnership, Decatur, Ga., and William W. McKinney and John Lewis Pledger, partners.

ALLEGED VIOLATION: Between November 1957 and 3–30–61, while quantities of imitation tablets of *Diuril, Dexedrine Sulfate* and *Dexamyl* were being held for sale after shipment in interstate commerce, the defendants caused such tablets to be repacked into bottles, which act resulted in such tablets being misbranded.

CHARGE: 502(a)—while held for sale, the label statements on the repack bottles "Tablets Diuril," "Dexedrine," and "Dexamyl" were false and misleading as applied to drugs which consisted of imitations of *Diuril, Dexedrine Sulfate,* and *Dexamyl;* 502(i)(2)—the articles were imitations of other drugs, namely, *Diuril, Dexedrine Sulfate,* and *Dexamyl;* 502(i)(3)—the articles were offered for sale under the names of other drugs, namely, *Diuril, Dexedrine Sulfate,* and *Dexamyl.*

DISPOSITION: 11–8–61. Partnership—$3,000 fine. Each partner—sentences of 1 year in prison suspended and probation for 3 years.

7043. **Herbs.** (F.D.C. No. 46207. S. Nos. 20–533/43 R.)

QUANTITY: 5 6-oz. pkgs. and 7 3-oz. boxes of *laxative herbs;* 1 15-lb. container and 3 6-oz. pkgs. of *Herbs No. 7;* 1 10-lb. container, 3 3-oz. pkgs., and 2 6-oz. pkgs. of *Herbs No. 28;* 1 10-lb. container, 4 3-oz. pkgs., and 5 6-oz. pkgs. of *Herbs No. 26;* 1 15-lb. container, 1 3-oz. pkg., and 4 6-oz. pkgs. of *Herbs No. 27;* 50 lbs. of anise seed; 50 lbs. of catnip; 100 lbs. of fennel seed; 2 75-lb. drums of peppermint leaves; 1 50-lb. drum of cascara; 1 35-lb. drum of cheeseplant; 50 lbs. of red clover tops; 100 lbs. of licorice root; 30 lbs. of American licorice; 15 lbs. of juniper berries; 75 lbs. of berberis root;

*See also Nos. 7004, 7007–7010, 7013, 7014, 7020, 7022, 7024–7029, 7032–7036.

35 lbs. of wintergreen; 50 lbs. of sassafras bark; 50 lbs. of scullcap; 50 lbs. of dog grass; 25 lbs. of buchu; 50 lbs. of India sage; and 35 lbs. of liferoot, at Lorain, Ohio, in possession of Devore Herbs Co.

SHIPPED: Prior to June 1958 and on or about 7–2–58 and 3–17–59, from Jersey City, N.J.

LABEL IN PART: (Pkg.) "Devore Laxative Herbs—Extra Strong * * * Devore Herbs Company, Vermillion, Ohio" and "Devore Herbs No. 7 [or "28" or "26" or "27"]."

ACCOMPANYING LABELING: Leaflets entitled "Sluggish Kidneys May Cause Backache, Getting Up Nights"; six pages of leaflets stapled together and entitled "Nature's Way is Best," with one page headed "Constipation" and one page headed "In Giving The Therapeutical Value of Botanicals In This page"; and repack labels and empty retail packages.

RESULTS OF INVESTIGATION: The articles were repacked and labeled by the dealer from bulk stock shipped as described above. The leaflets were prepared by the dealer and were used in promoting sales of the articles.

LIBELED: 8–15–61, N. Dist. Ohio.

CHARGE: 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that the various articles were adequate and effective as a treatment for use in eliminating body wastes and thereby preventing, overcoming, or relieving colds, coughs, piles, fever, backaches, and nerve conditions; and that herbal preparations were capable of relieving pain, expelling worms, curing rheumatism, preventing spasms, purifying the blood, cleaning boils and ulcers, curing ringworm and other skin diseases, and dispelling tumors.

DISPOSITION: 3–28–62. Consent—claimed by Theodore J. Risden, t/a Devore Herbs Co., Lorain, Ohio, and relabeled.

7044. Kiddy Kaps vitamins. (F.D.C. No. 47138. S. Nos. 9–680 T, 10–684 T.)

QUANTITY: 106 24-tablet btls., 5 cases, 24 100-tablet btls. each, and 6 cases, 12 250-tablet btls. each, of *Kiddy Kaps Tastitreat;* 17 32,000-tablet drums of *Kiddy Kaps Vitamin Chew tablets;* and 32 cases, 24 100-tablet btls. each, and 18 cases, 12 250-tablet btls. each, of *Kiddy Kaps Vitamin Treat*, at Buffalo, N.Y., in possession of Republic Drug Co., Inc.

SHIPPED: Between 11–9–61 and 12–29–61, from Englewood, N.J., and Cleveland, Ohio, to Buffalo, N.Y.

LABEL IN PART: (Btl.) "Kiddy Kaps Tastitreat Sugar Free Vitamin Treat for Children * * * Republic Drug Company, Inc., Buffalo, N.Y. Distributors"; (drum) "Manufactured For Republic Drug Company, Inc. Vitamin Chew Tablets"; and (btl.) "Kiddy Kaps Vitamin Treat for Children * * * Republic Drug Company, Inc., Distributors Buffalo, New York."

ACCOMPANYING LABELING: Streamers entitled "Kiddy Kap Childrens Vitamins"; place cards entitled "Free Reg. $1.00 Size Kiddy-Kaps"; newspaper advertisement mats and impressions of same reading, in part, "Fight Colds Build Strong Bodies * * * Kiddy Kaps"; and extra bottle labels.

RESULTS OF INVESTIGATION: The dealer had repacked the *Kiddy Kaps Tastitreat tablets* from bulk stock and the *Kiddy Kaps Vitamin Treat tablets* from the 32,000-tablet drums. The bulk stock and the drums had been shipped as described above. The accompanying labeling was printed locally.

LIBELED: 2–23–62, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of colds, to build strong bodies, and to stimulate appetites.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4–5–62. Consent—claimed by Republic Drug Co., Inc., and relabeled.

7045. Nutri-Health products. (F.D.C. No. 46798. S. Nos. 9–483/84 T.)

QUANTITY: 55 cases, 25 pkgs. each, of *Multi-Vitamin and Mineral Dietary Supplement* and 23 cases, 25 pkgs. each, of *Protein Plus Dietary Supplement*, at Pittsburgh, Pa., in possession of World-Wide Nutri-Health, Inc.

SHIPPED: 10–16–61 and 10–19–61, from Paramus, N.J.

LABEL IN PART: (Pkg.) "Natural or Organic Multi-Vitamin & Mineral Dietary Supplement * * * with exclusive Nutri-Zymes * * * 308 Mineral Tablets 184 Vitamin Tablets * * * Formulated for and Distributed by World-Wide Nutri-Health, Inc., Pittsburgh 20, Pa." and "Natural or Organic Protein plus Nutri-Zymes-P Dietary Supplement Fruit Flavor * * * 368 tablets * * * Formulated for and Distributed by World-Wide Nutri-Health, Inc., Pittsburgh 20, Pa."

ACCOMPANYING LABELING: Books entitled "Hunza Land, by: Dr. Allen E. Banik and Renee Taylor"; film kits entitled "Nutri-Health Highway" and "Bright Future For You"; sales manuals; folders entitled "Proteins structural basis of all living cells!" and "Health thru Natural Nutrition Vitamins and Minerals"; and booklets entitled "Man's Greatest Gifts . . . Good Health Vitality Zest For Living."

RESULTS OF INVESTIGATION: The accompanying labeling was printed and prepared on order of, or ordered by, the dealer.

LIBELED: 12–19–61, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the labeling, namely, the package label and promotional material accompanying the article, contained false and misleading representations that (*Multi-Vitamin and Mineral Dietary Supplement*), the article was adequate and effective for the treatment and prevention of circulatory diseases, cancer, heart attacks, mumps, measles, chicken pox, nervousness, cramps, wrinkles, and overweight conditions; to prevent juvenile delinquency; and to promote longevity, eternal youth, virility, optimism, radiant health, vitality, zest for living, sound eyesight, attractiveness until a ripe old age, and vigor; and the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of linoleic and linolenic acids, vitamin F, inositol, para-aminobenzoic acid, rutin, biotin, methionine, bioflavonoid complex, choline, chlorophyll, chlorophyllins, alfalfa juice and powder concentrate, manganese, magnesium, potassium, sulfur, chlorine, sodium, papain, Prolase, pepsin, and Mylase; that the article was a complete, balanced food supplement; that the American people are undernourished, although overfed, since it was impossible to obtain adequate nutrition in the ordinary food supplies; and that all the ingredients of the article were natural or organic, and were of special significance for special dietary supplementation because they were natural or organic; that (*Protein Plus Dietary Supplement*), the article

was adequate and effective to improve appetite; increase resistance to infections; raise hemoglobin level; fight virus and toxic invaders; promote energy, blood clotting, enzyme and hormone production, sound health, digestion, strength and athletic ability; to prevent "dragged-out" feeling, dry skin, wrinkles, premature old age, and cell starvation; and that the article was of significant value for special dietary supplementation and for therapeutic use by reason of the presence therein of natural protein and enzymes.

DISPOSITION: 3–9–62 and 3–20–62. Consent—articles ordered delivered for use of a charitable institution; literature and film kits destroyed.

7046. Geriatric vitamin capsules. (F.D.C. No. 46939. S. Nos. 25–902/3 T.)

QUANTITY: 139 ctns., 5,000 capsules each, 25 240-capsule carafes, 80 120-capsule btls., and 694 60-capsule btls., at Holland, Mich., in possession of The DePree Co.

SHIPPED: 6–15–61 and 8–16–61, from Newark, N.J.

LABEL IN PART: (Bulk) "Contains 5,000 Capsules 16 Minim Oblong–Black * * * Each Capsule Contains MDR * * * l-lysine Monohydrochloride 50 mg. * * * Choline Bitartrate 45 mg. * * * Inositol 30 mg. * * * Liver Desiccated NF 50 mg. Yeast, dried 50 mg. * * * Safflower Oil 300 mg." and (repack btl. and carafe) "DePree Geriatric Capsules 'After 40' Regimen Vitamin, minerals, and lipotropes * * * Contents: * * * Suggested Dose: * * * Two Capsules Provide: Vitamin B Complex Factors * * * l-lysine Monohydrochloride 100 mg. Choline bitartrate 90 mg. (providing Choline, 43 mg.) m-Inositol 60 mg. Other Vitamins * * * Natural Source Nutrients Liver, desiccated, NF 100 mg. Yeast, dried 100 mg. Safflower oil (unsaturated fatty acids) 600 mg. Minerals * * * Distributed by Nutritional Products Division The DePree Company Holland, Michigan."

ACCOMPANYING LABELING: Leaflets entitled "How to get the most from your vitamin-mineral program"; single sheets entitled "Which is best for YOU WheataVims or . . . Geriatric Capsules" and "With all the emphasis on Quality * * * Geriatric Capsules"; folders entitled "The DePree View"; booklets entitled "Facts About The Vitamins" and "Basic Concepts of Health"; leaflets entitled "For the prime of life . . . and after Geriatric Capsules"; and counter cards entitled "The Problem: Devitalized * * * Foods," "Low Cost Health Insurance," "This Doesn't Need To Happen," and "Vitamin Shortages shocked these Doctors."

LIBELED: 1–25–62, W. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the nutritional requirements of people over 40 are different from adults generally; that the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of the lipotropic and protein factors and natural source nutrients; that the article was a complete, balanced vitamin and mineral formula; and that the article was adequate and effective for the treatment and prevention of mental depression, the common cold, low energy, conditions due to stress and strain, poor health, degenerative diseases, all diseases, cardiovascular diseases, nervous ailments, rheumatism and rheumatic disorders, gastrointestinal disturbances, loss of appetite, diabetic and varicose ulcers, mental diseases, allergies, diminished ability, digestive disorder, improper clotting of blood, heart muscle deterioration, dropsy, retarded growth, and for other purposes.

DISPOSITION: 2–16–62. Certain pieces of the accompanying labeling having been seized and no capsules of the article having been found available for seizure, and The DePree Co. having consented to the entry of a decree, judgment of condemnation was entered and the labeling was ordered destroyed.

7047. Mineral Life capsules. (F.D.C. No. 45300. S. No. 23–318 R.)

QUANTITY: 25 20-capsule boxes at Oklahoma City, Okla.

SHIPPED: 10–8–60 and 10–10–60, from Logan, Utah, by Nutritional Progress Scientific Co.

LABEL IN PART: "MINERAL LIFE

Active Ingredients	
Silicon	Major ingredient
	Not More Than
Iron	0.5 to 2.0%
Calcium	0.2 to 1.5%
Magnesium	0.2 to 1.5%
Vanadium	0.5 to 1.5%
Titanium	0.3 to 1.0%
Copper	0.3 to 2.0%
Potassium	0.02 to 0.1%
Strontium	0.005 to 0.05%
Lead, Zirconium, Cobalt, Manganese	0.01 to 0.1%
Chromium, Molybdenum	0.0005 to 0.005%
Nickel	0.0001 to 0.001%

Dosage: 4 yrs. to 12 yrs.–1 capsule; 12 years and up–up to 5 capsules. This is a natural mineral. Not compounded by man. * * *

Nutritional Progress Scientific Co., 599 West Center, Logan, Utah."

ACCOMPANYING LABELING: Leaflets entitled "Mineralife And What It Means To You" and "Eject Death From The Temple"; and order blanks entitled "Mineral Life."

LIBELED: 12–30–60, W. Dist. Okla.

CHARGE: 502(a)—when shipped and while held for sale, the article's accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of cancer, cancer of the face, disease, illness, inefficient absorption of food, inefficient elimination, circulatory system coated and clogged with calcium and other sludge deposits, premature aging, starving body cells, toxic secretions, excessive moisture, fats and dead cell tissues, heart trouble, heart flutter and laborious pounding and breathlessness after strenuous exercise, sleeplessness, loss of appetite, shortness of breath following Asiatic flu, extreme tiredness; arthritis with soreness, weakness, stiffness, and throbbing; tumor, pain, severe stomach pain and failure to eat and sleep following flu, stomach trouble, colon trouble, ulcers, rheumatoid arthritis, pancreatic and stomach injuries, constipation, nervousness, weakness, bursitis, neuralgia, neuritis, heart palpitations, overweight condition, and anemic condition; and to eliminate any condition or substance which causes disease of the body; regulate body functions; control water balance; maintain acid-base equilibrium and promote utilization of foodstuffs; promote sound teeth and give rigidity and relative prominence to skeletal tissues; maintain elasticity and irritability of muscles and nerves; promote good health; become a relaxed, calmer person; promote strong, vibrant blood, and for pep; and 502(e)(2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: On 2–17–61, the shipper filed a claim, an answer, and a notice of a motion to remove the action to the District of Colorado. On 5–22–61, the action was transferred to the District of Colorado. On 9–13–61, the claimant, without admitting the allegations of the libel, consented to a decree of condemnation and destruction; an order adjudging the article misbranded and ordering its destruction was entered.

7048. B_{12} injection. (F.D.C. No. 46532. S. No. 18–681 T.)

QUANTITY: 593 10-cc. vials at San Antonio, Tex., in possession of Knight Pharmacal Co.

SHIPPED: 6–23–61 and 8–23–61, from Philadelphia, Pa.

LABEL IN PART: "10 cc Multiple-Dose Vial Crystalline Vitamin B_{12} * * * Distributed by Knight Pharmacal Co. San Antonio, Texas."

ACCOMPANYING LABELING: Carton insert, reading in part, "Vitamin B_{12} Injection."

LIBELED: 11–16–61, W. Dist. Tex.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective for treatment of neurological conditions, trigeminal neuralgia, multiple sclerosis, and neuro-anemic syndromes.

DISPOSITION: 12–20–61. Default—delivery to a public, charitable hospital.

7049. Lecitabs (lecithin tablets). (F.D.C. No. 46968. S. No. 34–677 T.)

QUANTITY: 56 90-tablet btls. and 13 180-tablet btls. at Minneapolis, Minn.

SHIPPED: Between 6–23–61 and 10–4–61, from Chicago, Ill., by National Lecithin, Inc.

LABEL IN PART: "National Lecitabs Lecithin Tablets A Natural Food Product Highly concentrated extra rich, Soya Lecithin formula of 95% oil free Phosphatides. Ingredients: Soya Lechithin, in a base of non-fat, dry milk solids and soy protein. Natural flavoring added. Sole Distributors: National Lecithin, Inc. Chicago 26, Ill. * * * a dietary supplement of natural lipotropic factors. * * * a rich, natural source of Lecithin, Cephalin, Choline and Inositol Phosphatides * * * rich in both linoleic and linolenic acids."

LIBELED: 2–20–62, Dist. Minn.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective to promote utilization of fat and to lower blood cholesterol.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4–6–62. Default—destruction.

7050. Alfalfa tablets. (F.D.C. No. 46463. S. No. 81–971 R.)

QUANTITY: 1 drum, containing approximately 29,000 tablets, at Forest, Miss., in possession of Pasco Products. Inc.

SHIPPED: 6–27–61, from North Kansas City, Mo.

LABEL IN PART: "Alfalfa Tablets, Red."

ACCOMPANYING LABELING: Folder entitled "Alfa-Lite In Liquid or Tablet"; and package label reading in part "100 Tablets Alfa-Life Concentrated Alfalfa Extract 100 Mg. in each tablet. For the treatment of joint pains and stiffness resulting from arthritic and rheumatic like conditions * * * Distrib-

uted by Pasco Products, Inc., Forest, Miss. * * * made from the water soluble extract of organically grown alfalfa."

RESULTS OF INVESTIGATION: The dealer had prepared and printed the accompanying labeling and had used it in promoting sales of the article. In the normal course of the dealer's business operations, the tablets were repacked into packages bearing the above package label.

LIBELED: 9–20–61, S. Dist. Miss.

CHARGE: 502(a)—while the article was held for sale, its accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment of arthritis, rheumatism, sciatica, bursitis, body aches and pains, and joint swellings.

The libel alleged also that the article, when shipped, was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–24–62. Default—destruction.

7051. Special dietary supplements. (F.D.C. No. 46934. S. Nos. 51–667/72 T.)

QUANTITY: 1 14,000-tablet drum and 1 10,000-tablet drum of *SF #7523;* 15 40-tablet btls., 5 100-tablet btls., and 8 200-tablet btls. of *Menzyme;* 1 10,000-tablet drum and 1 13,500-tablet drum of *SF #7524;* 40 40-tablet btls., 15 100-tablet btls., and 18 200-tablet btls. of *Femzyme*; 1 10,000-tablet drum and 1 13,500-tablet drum of *SF #7525;* 11 40-tablet btls., 24 100-tablet btls., 4 200-tablet btls. of *Penezyme;* 1 15,000-tablet drum and 1 7,000-tablet drum of *SF #7522;* 60 60-tablet btls., 74 100-tablet btls., 137 180-tablet btls., 22 400-tablet btls., and 10 1,000-tablet btls. of *Homale;* 1 29,000-tablet drum of *SF #7526;* 10 40-tablet btls., 8 100-tablet btls., 27 200-tablet btls., 4 400-tablet btls., and 3 1,000-tablet btls. of *Prostaid;* 1 10,000-tablet drum of *SF #7641;* and 128 30-tablet btls., 87 100-tablet btls., 106 200-tablet btls., and 7 400-tablet btls., of *Gestran*, at Portland, Oreg., in possession of Central Drug Co.

SHIPPED: Between 8–4–61 and 10–12–61, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Drum) "10–M Tablets Special Formula SF #7523 * * * Yellow Each tablet contains: Cobalamin Conc. (Vit. B–12 Act.) 5 meg. Thiamine Chloride 10 mg. Ascorbic Acid 25 mg. Mylase 1 mg. Prolase 1 mg. Cellulose 1 mg. Pyridoxine 2.5 mg. * * * Dose: As a dietary supplement * * * Caution: * * * Control #27706 Richlyn Laboratories, Phila., Penna."; (btl.) "Menzyme Enzyme-Vitamin Formula Daily Dose provides: Enzyme-x (Raymo brand name for combination of Amylolytic, Proteolytic, and Cellulolytic enzymes) (each) 200 mcg. Cobalamin Concentrate (Vitamin B–12 activity) 10.0 mcg. Thiamin Chloride (Vitamin B–1) 20.0 mg. Riboflavin (Vitamin B–2) 5.0 mg. Pyridoxine (Vitamin B–6) 5.0 mg. Ascorbic Acid (Vitamin C) 50.0 mg. Sold in Oregon only by Central Drug. Co. * * * Portland, Oregon * * * Distributed by Raymo Laboratories Portland Ore. * * * 100 Tabsules"; (drum) "7523–25 13,500 Tablets Special Formula SF #7524 * * * Green Control #27697"; (btl.) "Femzyme Enzyme-Vitamin Formula * * * 27696"; (drum) "7523–25 13,500 Tablets * * * Special Formula SF #7525 * * * White * * * Control #27698"; (btl.) "Penezyme Enzyme-Vitamin Formula * * * 27698"; (drum) "15,000 Tablets Special Formula SF #7522 * * * Green Each tablet contains * * * Dose: As a dietary supplement * * * Caution: * * * Control #27405 Richlyn Laboratories Phila., Penna."; (btl.) "Homale Nutritional Supplement Each two capsules

provide the following vitamins, minerals and glandular substances: * * * New Formula Fortified with Enzymes * * * Manufactured for and distributed by Raymo Laboratories Portland, Oregon * * * Sold in Oregon Only by Central Drug Co., 538 S.W. 4th Ave., Portland, Ore. Contains 100 capsules"; (drum) "29,000 Tablets Special Formula SF #7526 * * * Pink Each tablet contains * * * Dosage: * * * Caution: * * * Control #27466 Richlyn Laboratories, Phila., Penna."; (btl.) "Raymo Laboratories Prostaid Valuable Geriatric Tonic & Diuretic For Aging Men Contains 100 capsules Dose: * * * Manufactured For & Distributed by Raymo Laboratories, Portland, Oregon Sold in Oregon only by Central Drug Co. * * * Portland, Oregon"; (drum) "25,000 Tablets Special Formula SF #7641 * * * Blue Each Tablet Contains: Pectin Cellulose Compalex 0.5 gr. Glysine 1½ gr. Calcium Carbonate 7½ gr. Hematropine Methyl Bromide 0.5 mg. Aluminum Hydroxide Gel 1½ gr. as an aid in the relief of Hyperacidity * * * Caution:"; and (btl.) "Tablets Gestran For Prompt Relief of Stomach Distress due to gastric hyperacidity and hypermotility * * * For Adults Only Dose: * * * Manufactured for and Dist. by Raymo Company, Portland, Oregon * * * Sold in Oregon only by Central Drug Co."

ACCOMPANYING LABELING: Reprints of "Reader's Digest" magazine article, entitled "Enzymes Medicine's Bright Hope"; placards entitled "New Release For Prostate Gland"; and repack labels.

RESULTS OF INVESTIGATION: The bottled articles of drug described above were repacked by the dealer from the bulk drums of drug described above.

LIBELED: 1–26–62, Dist. Oreg.

CHARGE: 502(a)—(*Menzyme*, *Femzyme*, *Penezyme*, and *Homale* bulk and repack) when shipped and while held for sale, the labeling contained false and misleading representations that the articles were of significant value for special dietary supplementation by reason of the presence therein of (*Homale*) proteolytic enzyme, glycine, alanine, glutamic acid, stomach substance, liver substance, and methionine; and (*Menzyme*, *Femzyme*, and *Penezyme*) Enzyme-x, containing amylolytic, proteolytic and cellulolytic enzymes; and the labeling accompanying the articles also contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of cancer, high blood pressure, diabetes, and leukemia, and to dissolve blood clots, build muscles, stay the aging process, and for other purposes; and (*Prostaid* and *Gestran* bulk and repack) while held for sale, the labeling contained false and misleading representations that the articles were adequate for the treatment of (*Prostaid*) the disease and enlargement of the prostate gland and (*Gestran*) stomach disorders due to hypermotility.

DISPOSITION: 3–8–62. Consent—claimed by Central Drug Co. and relabeled.

7052. Olive oil. (F.D.C. No. 47204. S. No. 54–099 T.)

QUANTITY: 50 55-gal. barrels, 79 cases, 12 1-qt. cans each and 54 cases, 6 1-gal. cans each, at Detroit, Mich., in possession of Mario's Food Products Co.

SHIPPED: 11–4–61, from Reus and Córdoba, Spain.

LABEL IN PART: (Can) "Mario's Cream Virgin Imported Olive Oil Mario's Food Products Co., Detroit, Mich."

RESULTS OF INVESTIGATION: The article in the cans was repacked by the dealer from the bulk lots described above.

LIBELED: 3–6–62, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to promote health, strength, long life, and physical resistance to disease; to stimulate the appetite; and to aid digestion.

DISPOSITION: 3–23–62. Consent—claimed by Mario's Food Products Co. and relabeled.

7053. Moxley Two-In-One massage pillow. (F.D.C. No. 42536. S. No. 15–330 P.)

QUANTITY: 5 devices at Columbus, Ohio.

SHIPPED: 9–20–58, from Los Angeles, Calif., by Moxley Massage Equipment Co., Inc.

LABEL IN PART: "Moxley Two-In-One Massage Pillows."

ACCOMPANYING LABELING: (Sales manuals) "Moxley Two-In-One Thera-Massage"; (booklets) "A Heart to Heart Story"; and (leaflets) "How to Enjoy the Famous Moxley Two-In-One Massage Pillow."

LIBELED: 12–1–58, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for heart disease, hypertension, poor circulation which may lead to arthritis, bursitis, ulcers, constipation, stomach stricture, kidney inflammation, sclerosis of the liver, or "dozens of other terrible illnesses"; spastic paraplegia and fibrositis; fallen arches; sinus congestion; paralysis due to strokes; migraine headaches; and for diabetes, hives, and baldness.

DISPOSITION: 3–3–60. Default—the devices and a portion of the accompanying labeling delivered to the Food and Drug Administration; remainder of accompanying labeling destroyed.

7054. Tone Facial Exercise device. (F.D.C. No. 45706. S. No. 57–640 R.)

QUANTITY: 47 devices at Miami, Fla.

SHIPPED: 11–9–60 and 12–7–60, from Beverly Hills, Calif., by Tone International.

LABEL IN PART: "Tone Facial Exercise * * * Gabrielle Products, Fullerton, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Operating Instructions–Tone Facial Exerciser," "You Cannot Pull or Stretch a Muscle * * * Tone Facial Exerciser," and "Read This Before Using The Electronic Facial Exerciser."

RESULTS OF INVESTIGATION: Examination showed the article to be similar in size and general shape to an electric shaver. It consisted of a plastic housing containing a small electric motor and an electric cord for connection to ordinary household current. Attachments consisted of two plastic sponges which might be affixed to either side of the device. Two switches reportedly controlled, at a high or low level, the "contractions" action of the sponges as they were placed next to the skin of the facial area.

LIBELED: 4–11–61, S. Dist. Fla.

CHARGE: 502(a)—when shipped, the name "Tone" and statements in the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for aiding in erasing wrinkles, sagging muscles, heavy jowls, double chin, crepy throat, crow's feet, lines around the eyes, lines in the forehead, lines in front of ears, lines on side of the mouth, circles under the eyes, and loose cheek muscles; toning and firm-

ing facial muscles; and providing eye exercise, leaving the eyes refreshed and sparkling bright.

DISPOSITION: 6–22–61. Default—destruction of all devices except for 25 which were delivered to the Food and Drug Administration.

7055. Rejuvené device. (F.D.C. No. 45952. S. Nos. 52–815/16 R.)

QUANTITY: 77 devices at Minneapolis, Minn., in possession of Rejuvené, Inc. Each device was in a carrying case-type container in which was included a bottle of lotion.

SHIPPED: 4–21–61, from Los Angeles, Calif. This was a return shipment.

LABEL IN PART: (Device) "Rejuvené" and (btl.) "Rejuvené Lotion."

ACCOMPANYING LABELING: Leaflet and booklet entitled "For your face of the future"; sheet entitled "Owner's Participation Bond"; leaflets entitled "Rejuvené Product Knowledge," "TV Time & Talent Cost," and "What do Leading Beauty Editors Have to Say About The 'Anti-Wrinkle Campaign'"; folder entitled "Vogue's New Beauty Book"; card entitled "Rejuvené Owner Register"; leaflet and folder entitled "Does Your Face Show your Age"; pamphlets entitled "Representative's Instruction Data," "Sales Presentation," and "Telephone Solicitation following up a mailing."

RESULTS OF INVESTIGATION: Examination indicated the device to be a plastic-covered case containing a mirror, a battery-powered transistorized electronic circuit, applicator electrodes, sponges and a bottle of lotion. The case was approximately 9½" x 11½" x 5". The device produced an electric current to the skin through the applicator sponges.

LIBELED: 6–28–61, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for regaining and retaining a youthful face and throat by overcoming lines in the area of the forehead, eyes, nose, mouth, chin, neck, and throat; eliminating wrinkles and teen-age skin problems; toning and firming sagging and weakened muscles; and stimulating circulation to rejuvenate the facial tissues.

DISPOSITION: 8–10–61. Default—destruction.

7056. Jacuzzi Whirlpool Bath. (F.D.C. No. 47200. S. No. 9–320 T.)

QUANTITY: 14 individually ctnd. devices at Buffalo, N.Y., in possession of Chester Lehr, Inc.

SHIPPED: 8–29–61, from Hackensack, N.J., by Jacuzzi Bros., Inc.

LABEL IN PART: (Tag on device) "Jacuzzi Whirlpool Bath"; (ctn.) "New–Compact–Portable Jacuzzi Whirlpool Bath For Use In Any Therapy Tank or Bathtub Manufactured by Jacuzzi Research, Inc., 1440 San Pablo Avenue, Berkeley, California."

ACCOMPANYING LABELING: Letters addressed to "Dear Doctor" and promotional letters reading in part "After years of development a Hydromassage unit is now available for use in the home."

RESULTS OF INVESTIGATION: The promotional letter reading in part "After years of development . . ." was prepared by the dealer.

LIBELED: 3–12–62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for relieving pain of arthritis, bursitis, rheumatism, and other muscular disorders; relieving varicose veins, hemorrhoids, restricted circulation of the extremities, and nervous tension; reviving muscular and skin tissue; and accomplishing bone regeneration.

DISPOSITION: 3–26–62. Consent—claimed by Chester Lehr, Inc., and released under bond for relabeling.

7057. Acme Juicerator device. (F.D.C. No. 46964. S. No. 11–003 T.)

QUANTITY: 38 devices at Buffalo, N.Y.

SHIPPED: 12–9–61, from Lemoyne, Pa., by Acme Juicer Manufacturing Co.

LABEL IN PART: (Device) "Acme Supreme Model 5001 Serial No. 47841 * * * Acme Mfg. Co. 34 N. Baldwin, Sierra Madre, Calif."

ACCOMPANYING LABELING: Books entitled "Natural Raw Vegetable and Fruit Juices"; folders entitled "Nectar of Fruits and Vegetables . . . Extracted Fresh Daily with the Acme Juicerator"; mimeographed booklets entitled "Presenting The Natural Approach to Good Health"; and books entitled "Live Food Juices."

LIBELED: 2–9–62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was the answer to having vitality and good health; that the article was a "Gold Mine" investment in good health; that it made (juice) cocktails rich in vitamins; that it was the most valuable appliance in the home; and that, by reason of its health significance and its use in extracting raw fruit and vegetable juices, the article was beneficial in the treatment of colds, cancer, ulcers, arthritis, intestinal complaints, and other disease conditions.

DISPOSITION: 3–27–62. Consent—claimed by Acme Supreme of New York, Inc., Buffalo, N.Y., and relabeled.

7058. Figurette device. (F.D.C. No. 46477. S. No. 51–065 R.)

QUANTITY: 5 devices at Greeley, Colo.

SHIPPED: 6–16–61, from Grand Prairie, Tex., by A.R.A. Manufacturing Co.

LABEL IN PART: "A.R.A. Figurette Mfg. by ARA Mfg. Co."

ACCOMPANYING LABELING: Pamphlets entitled "The Sure Way," "A Graceful Way," "A Manly Way," "Effortless Exercise," and "How to use Figurette"; card entitled "Figurette Progress and Service Chart"; wall placard entitled "Figurette The Graceful Way to Physical Beauty"; sales brochure entitled "Figurette . . . Your Personal Salon"; and catalogue of Figurette advertising mats.

RESULTS OF INVESTIGATION: Examination indicated that the article consisted of a box-shaped housing containing a timer-controlled electric motor capable of providing vibration to four upholstered pads attached above the motor housing. Collapsible foot and head rests extended from the ends of the rectangular-shaped housing.

LIBELED: 10–4–61, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for reproportioning the entire body, relieving many daily tensions,

correcting posture, stimulating circulation, tightening and toning muscle tissues, removing excess fatty tissue, reducing weight and slenderizing, firming the flesh, spot reducing, relieving tension while conditioning the body, and recontouring the figure.

DISPOSITION: 1–12–62. Default—2 devices delivered to the Food and Drug Administration; the remaining 3 devices destroyed.

7059. Puritron device. (F.D.C. No. 43635. S. No. 5–639 P.)

QUANTITY: 7 Model F–20 devices and 5 Model 800 devices, at Wash., D.C.

SHIPPED: 9–1–59 and 9–4–59, from New Haven, Conn., by Puritron Corp.

LABEL IN PART: (Device) "Puritron * * * Model * * * New Haven, Conn."

ACCOMPANYING LABELING: Placards reading "Who's afraid of the Pollen Count?" and "This Week Try Puritron"; leaflets entitled "Important Medical Notice" and "Facts About Puritron."

RESULTS OF INVESTIGATION: Photographs and labeling indicated the article consisted of a portable box-type cabinet containing an electric fan, fiber filter pad, and several ultraviolet lamps. In operation, the fan would draw room air into the cabinet where it would pass through the filter and be exposed to ultraviolet lamps, after which it was expelled back into the room.

LIBELED: 10–29–59; libel amended 3–1–61 and 12–15–61, Dist. Columbia.

CHARGE: (Original libel), 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for relieving hay fever, asthma, sinus, and allergies; that use of the device would relieve "desperate sufferers" of allergy conditions; that the device was an advance in the field of allergy relief; that it allowed sinus, asthma, or allergy sufferers to breathe freely without fear of coughing, sneezing, or wheezing; and that the device was used by physicians and in hospitals, thereby implying that the device had an established position as an effective treatment for the named conditions; and (first amendment to libel), 502(a)—when shipped, the labeling for the device, namely, the leaflet entitled "Important Medical Notice" also contained the following statement, " 'Surpasses all expectations. Performs miracles for a dust allergy patient.'–A Pennsylvania Physician." which statement was false and misleading in that it represented that the person making the statement was a physician whereas such person was not a physician, and in that it represented that the device would perform miracles for a dust-allergy patient, whereas the device would not accomplish such results.

DISPOSITION: On 12–7–59, Puritron Corp., claimant, filed an answer denying that the article was misbranded. Thereafter, on 3–1–61, the Government filed an amendment to the libel, to which claimant filed an answer admitting that the person to whom the labeling statement quoted in the amendment to the libel was attributed was not a physician, but denying that the statement was false and misleading in any other respect.

On 12–15–61, the Government filed a second amendment to the libel, praying for injunctive relief. On 12–20–61, the claimant having admitted the allegations contained in the first amendment to the libel and denying the substantive allegations in the remainder of the libel and having consented to a decree, and the Government having consented to dismissal of the prayer for injunctive relief, the court adjudged that the article was misbranded under 502(a) as alleged in the amended libel and entered a decree providing for condemnation and destruction of the article, and dismissal of the prayer for injunctive relief.

DRUG FOR VETERINARY USE*

7060. Animal feed. (F.D.C. No. 47060. S. No. 29–223 T.)

QUANTITY: 70 50-lb. bags at Waterloo, Iowa.

SHIPPED: 7–17–61 and 8–8–61, from Boscobel, Wis., by Hess Buttermilk Co.

LABEL IN PART: (Bag) "Hess Stoc-Mix Rich In Health and Growth Factors From Condensed and Fermented Whole Whey Manufactured By Hess Buttermilk Co. Boscobel, Wis."

ACCOMPANYING LABELING: Leaflets entitled "Hess Milk Products Stoc-Mix" and "Don't Mix Without Stoc-Mix."

LIBELED: 2–28–62, N. Dist. Iowa.

CHARGE: 502(a)—the labeling contained false and misleading representations that the article was adequate and effective for the treatment of enteritis and necro in hogs, milk fever in sows, coccidiosis in turkeys and chickens, and intestinal troubles in stock animals; promoted vigor, high livability, health, and growth; developed bone and tissue; and built disease resistance.

DISPOSITION: 3–30–62. Consent—claimed by Hess Buttermilk Co., and released under bond for relabeling.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 7001 TO 7060

PRODUCTS

*See also Nos. 7037, 7038, 7040.

[1] (7029, 7059) Seizure contested.

[2] (7015) Seizure contested. Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (7029, 7059), Seizure contested.
[2] (7015) Seizure contested. Injunction issued.
[3] (7001) Injunction issued.

[1] (7029, 7059), Seizure contested.
[2] (7015) Seizure contested. Injunction issued.
[3] (7001) Injunction issued.

[1] (7029, 7059) Seizure contested.

U.S. GOVERNMENT PRINTING OFFICE: 1963

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7061-7120

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and including, in one case, the entry of a decree of injunction; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere, and, in one case, upon a verdict of not guilty after trial by jury; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 8, 1963.*

CONTENTS*

*For presence of a habit-forming substance without warning statement, see No. 7072; omission of, or unsatisfactory, ingredients statements, Nos. 7062, 7072, 7084, 7090; an imitation of, and sale under name of, another drug, No. 7092; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7084, 7090; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7071, 7072, 7089, 7090; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 7084; cosmetic, actionable under the drug provisions of the Act, No. 7119.

691-269—63——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 7061–7120

Adulteration, Section 501(a)(1), the article consisted in part of a filthy, putrid, or decomposed substance; Section 501(a)(2), the article had been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man, and contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulation designated as, habit forming, and its label failed to bear the statement "Warning—May be habit forming."; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear, in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, or a derivative of chlortetracycline, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

7061. Pan-Va-Tol. (F.D.C. No. 45779. S. No. 70–384 R.)

QUANTITY: 26 ctns., 12 8-oz. btls. each, at Waterbury, Conn.

SHIPPED: 10–2–59, from Worcester, Mass., by Brewer & Co., Inc.

LABEL IN PART: (Btl.) "Pan-Va-Tol * * * Each fluid ounce contains: * * * Folic Acid 1 mg. * * * Directions: One or two teaspoonfuls two or three times daily."

LIBELED: On or about 5–15–61, Dist. Conn.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage and with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: 2–17–62. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7062. Pangamic Acid capsules and Vi-Cardia capsules. (F.D.C. No. 45559. S. Nos. 1–412 P, 42–484/5 P.)

INFORMATION FILED: 11–16–61, N. Dist. Calif., against John Beard Memorial Foundation, an association, San Francisco, Calif., and Ernst T. Krebs, Jr.

SHIPPED: Between 7–30–58 and 8–19–59, from California to Oregon and Florida.

LABEL IN PART: (Bag tag) "JOHN BEARD MEMORIAL FOUNDATION P.O. Box 685 San Francisco, Calif. Pangamic Acid (Vitamin B-15) 2100 Blue-Gold Capsules 75 (mg.) 555 grams [or "500 Capsules Vi-Cardia Net wt: 205 grams Count: 100 capsules to 40 grams"]."

CHARGE: 502(e)(2)—(*Vi-Cardia capsules*) when shipped, the label of the article failed to bear the common or usual name of each active ingredient; 502(f)(1)—(*Pangamic Acid capsules and Vi-Cardia capsules*) the labeling failed to bear adequate directions for use; and 505(a)—the articles were new drugs within the meaning of the law and an application filed pursuant to 505(b) was not effective with respect to such drugs.

PLEA: Guilty.

DISPOSITION: 5–3–62. John Beard Memorial Foundation—$5.00 fine; Ernst T. Krebs, Jr.—$3,750 fine, sentencing under imprisonment section suspended, and probation for 3 years.

7063. Entoquel with Neomycin syrup. (F.D.C. No. 46221. S. No. 93–621 R.)

QUANTITY: 46 6-oz. btls. at Seattle, Wash.

SHIPPED: 2–3–61, from San Leandro, Calif., by Schering Corp.

LABEL IN PART: (Btl.) "Entoquel with Neomycin Syrup Caution: * * * White Laboratories, Inc., Kenilworth, New Jersey Dosage: * * * Each Teaspoon (5 cc.) contains * * * Thihexinol (Entoquel) 5 mg. Neomycin (from the sulfate) 50 mg. Alcohol 0.5%."

ACCOMPANYING LABELING: Letters addressed "Dear Doctor" and folders entitled "are opiates now outmoded in pediatric diarrhea?"

LIBELED: 7–31–61, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the drug would successfully treat diarrhea which threatened pediatric patients, without side effects; that the

drug "acts almost exclusively to inhibit gastrointestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine like effects when given in the recommended dosage" and that "the only side effect noted was a mild, more or less transient flushing of the skin"; and that the article stopped diarrhea rapidly without side effects; 502(f)(1)—the labeling failed to bear adequate directions for use and it was not exempt from that requirement; 505(a)—the article was a new drug which may not be introduced into interstate commerce since the new drug application filed with respect to the article did not apply to the conditions for which the article was promoted to the medical profession, namely, for the treatment of complications of severe pediatric diarrhea – dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen, constant crying, nonspecific digestive upsets, and for nausea and vomiting.

DISPOSITION: 2–12–62. Default—destruction.

7064. Instant Pain Reliever. (F.D.C. No. 47429. S. No. 40–773 T.)

QUANTITY: 18 cases, 12 11-oz. cans each, at Yonkers, N.Y., in possession of Scott Mitchell House, Inc.

SHIPPED: 3–2–62, from Philadelphia, Pa., by O'Neill Brands Co., Inc.

LABEL IN PART: (Can) "Instant Pain Reliever * * * Contents Trichloromonofluoromethane Dichlorodifluoromethane Essential Oils * * * Made Only By Instant Products Co. 5916 Green Street Philadelphia 44, Pa."

ACCOMPANYING LABELING: Copies of 1962 Spring Catalog of the Scott Mitchell House, Inc.

RESULTS OF INVESTIGATION: Inspection disclosed that the product was not made by Instant Products Co.

LIBELED: 4–10–62, S. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the label statement "Made Only By Instant Products Co." was false and misleading; 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions for which it was intended; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 5–4–62. Default—destruction.

7065. Chymotrypsin injection. (F.D.C. No. 47169. S. No. 30–787 T.)

QUANTITY: 352 individually ctnd. vials at Phoenix, Ariz.

SHIPPED: 11–21–61 and 1–30–62, from Los Angeles, Calif., by Injectable Pharmacal Co.

LABEL IN PART: (Vial and ctn.) "Chymotrypsin Injection * * * Mfg. for Rocky Mountain Pharmacal Phoenix, Arizona."

LIBELED: 3–13–62, Dist. Ariz.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 5–21–62. Default—destruction.

7066. Chymotrypsin injection. (F.D.C. No. 47042. S. No. 20–100 T.)

QUANTITY: 66 individually ctnd. vials at San Antonio, Tex.

SHIPPED: 12–29–61, from Los Angeles, Calif., by Injectable Pharmacal Co.

LABEL IN PART: (Vial and ctn.) "5 cc. Sterile Multiple Dose Vial Chymotrypsin Injection Each cc. Contains * * * Mfg. for Advance Drug Co. San Antonio, Texas * * * Caution."

ACCOMPANYING LABELING: Leaflet entitled "Chymotrypsin Injection Description * * * Action * * * Indications."

LIBELED: 2–16–62, W. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 5–25–62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

7067. **Prescription drugs.** (F.D.C. No. 47721. S. Nos. 7–971/3 T.)

QUANTITY: 9 100-capsule btls. and 1 36-capsule btl. of *Achromycin* and 4 100-capsule btls. of *Declomycin* at Providence, R.I.

SHIPPED: Delivered in person by a Lederle salesman prior to 6–18–62.

LABEL IN PART: (Btl.) "Lederle Achromycin V [or "Achromycin"] Tetracycline Hydrochloride * * * 250 mg. Capsules" and "Lederle Declomycin Hydrochloride Demethylchlortetracycline Hcl Crystalline Capsules 150 mg."; (each btl. also labeled) "Lederle Laboratories Division of American Cyanamid Company, New York, N.Y."

LIBELED: 7–13–62, Dist. R.I.

CHARGE: 502(l)—while held for sale, the articles were composed in part of derivatives of chlortetracycline and they were not from batches with respect to which certificates or releases had been issued pursuant to 507 since the removal of control numbers from the labels had caused the certificates to expire.

DISPOSITION: 8–15–62. Default—destruction.

DRUGS FOR VETERINARY USE

7068. **Medicated feeds.** (F.D.C. No. 46598. S. Nos. 15–518/19 T.)

QUANTITY: 186 50-lb. bags of *Tuxedo Chick Starter* and 19 50-lb. bags of *Tuxedo Pig Grower* at Ashland, Ky.

SHIPPED: On 8–15–61 and 9–27–61, from Cincinnati, Ohio by Early & Daniel Co.

LABEL IN PART: (Tag) "Tuxedo Chick Starter Medicated: For Prevention of outbreaks of Coccidiosis and growth stimulation * * * Active Drug Ingredients: Nitrofurazone 0.0083% 3-Nitro-4-Hydroxyphenylarsonic Acid 0.005% * * * Ingredients: * * * Penicillin * * * Made by The Early & Daniel Co., Cincinnati, Ohio" and "Tuxedo Pig Grower Medicated For growth stimulation and increased feed efficiency * * * Active Drug Ingredient: Arsanilic Acid 0.01% * * * Ingredients: * * * Bacitracin, Penicillin * * * Made by The Early & Daniel Co., Cincinnati, Ohio."

RESULTS OF INVESTIGATION: Analysis showed that the article, *Tuxedo Pig Grower*, contained less than the declared amount of arsanilic acid.

LIBELED: 10–23–61, E. Dist. Ky.

CHARGE: *Tuxedo Chick Starter*, 502(l)—when shipped, the article contained penicillin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

Tuxedo Pig Grower, 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Arsanilic Acid 0.01%" was false and misleading as applied to a product containing less than the declared amount of arsanilic acid; and 502(f)(2)—the labeling of the article failed to bear the warning statement "Discontinue use at least 5 days before slaughtering for human consumption."

DISPOSITION: 12–4–61. Default—destruction.

7069. Medicated feed. (F.D.C. No. 47157. S. Nos. 47–745/6 T.)

QUANTITY: 38 50-lb. bags at Memphis, Tenn.

SHIPPED: Between 6–23–61 and 7–10–61, from East St. Louis, Ill., by Dixie Mills Co.

LABEL IN PART: (Tag) "Dixie Medicated Turkey Starter * * * Active Drug Ingredient: Furazolidone (NF–180) 0.011% * * * Ingredients * * * Procaine Penicillin * * * Manufactured by Dixie Mills Company, East St. Louis, Ill. * * * Directions on Reverse Side" and "Dixie Medicated Snapback * * * Active Drug Ingredients: Oxytetracycline (Terramycin) Hydrochloride .05 grams per lb. (100 grams per ton) * * * Ingredients * * * Procaine Penicillin * * * Manufactured by Dixie Mills Company, East St. Louis, Illinois."

LIBELED: 2–26–62, W. Dist. Tenn.

CHARGE: 502(l)—when shipped, the articles were composed in part of procaine penicillin and they were not from batches with respect to which a certificate or release had been issued pursuant to 507, and they were not exempt from such certification since their labels represented that the articles were intended for use in the following conditions, namely, (Turkey Starter) "an aid in the control of CRD (air sac), synovitis (arthritis due to a filterable agent), nonspecific enteritis, bluecomb (Mud-Fever)" and (Snapback) "For * * * treatment of * * * synovitis (arthritis) due to a filterable agent in chickens and turkeys"; "For prevention and treatment to reduce losses from infectious diarrhea (necro), bloody scours and baby pig diarrhea in swine"; and "For an aid in reducing the incidence of scours in calves," and such conditions were not set forth in the exemption from certification regulations for animal feeds having the composition of the articles.

DISPOSITION: 4–5–62. Consent—claimed by Dixie Mills Co. and released under bond for relabeling.

7070. Procaine penicillin G in aqueous suspension (veterinary). (F.D.C. No. 46910. S. No. 41–510 T.)

QUANTITY: 2 ctns., each containing 3 inner ctns. of 10 boxes each, with 10 vials in each box and 1 ctn., containing 12 inner ctns., containing a total of 1,175 vials, at New York, N.Y.

SHIPPED: 10–16–61, from Philadelphia, Pa.

LABEL IN PART: (Inner ctn.) "100 No. 320 Procaine Penicillin G In Aqueous Suspension"; (box) "No. 320 Procaine Penicillin G"; and (vial) "Pen-AQ 10 cc. Multiple Dose Sterile Vials Procaine Penicillin G in Aqueous Suspension 300,000 units per cc For Veterinary Use Only * * * Control No. * * * Exp. Date Aug. 1961."

RESULTS OF INVESTIGATION: The expiration date had expired and no extension had been granted.

LIBELED: 1-12-62, S. Dist. N.Y.

CHARGE: 502(l)—while held for sale, the article was a drug composed wholly or in part of procaine penicillin and it was not from a batch with respect to which a certificate or release was in effect, and it was not exempted from such certification under 507(c) since the date of expiration had been reached.

DISPOSITION: 3-8-62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

7071. Various prescription drugs. (F.D.C. No. 46969. S. Nos. 14-861/73 T.)

QUANTITY: 800 vials, pkgs., and btls. at Chicago, Ill., in possession of Norwest Prescription Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "Complimentary," "Clinical Trial Supply," and "Physician's Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Illinois, the complimentary-professional sample legend, and the names and addresses of the manufacturers, packers, or distributors outside the State of Illinois; and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of Illinois.

LIBELED: 2-5-62, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the complimentary-professional sample legend on the labels of the articles was false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary-not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the repacked articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f)(1)—the labeling of a number of the repacked articles of drug failed to bear adequate directions for use and were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs; 503(b)(4)—a number of the repacked articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3-1-62. Default—destruction.

7072. Various articles of drug. (F.D.C. No. 46465. S. Nos. 1-964/5 R, 1-967 R, 2-978/80 R.)

QUANTITY: 80 ctns., 12 25-capsule btls. each and 54 ctns., 12 60-capsule btls. each, of *Slumba-Rest;* 49 ctns., 12 48-tablet btls. each, of *Nulpain;* 11 50-tablet btls. of *Seco-Synatan;* 71 ctns., 12 15-capsule btls. each, of *Pyrahist "C" Cold capsules;* 1 ctn., containing 12 40-tablet btls. of *Urettes;* and 100

90-capsule boxes and 100 45-capsule boxes of *Gelatins*, at Miami, Fla., in possession of Everglade Drug Co., Inc.

SHIPPED: Between 5–27–58 and 6–6–61, from Long Island City, N.Y., Decatur, Ill., and Philadelphia, Pa.

LABEL IN PART: (Btl.) "Slumba-Rest Aid forRestless Sleep Relieves Nervousness"; "Nulpain Fast Relief Pain Reliever"; "Seco-Synatan I. Neisler"; "Pyrahist 'C' Cold Capsules"; "Urettes Urinary Antiseptic"; and (box) "Gelatins Non-Fattening."

ACCOMPANYING LABELING: Counter display cartons reading in part "Slumba-Rest Aid for Restful Sleep" and "Urettes"; carton display sticker labels reading in part "Nulpain Fast Pain Reliever," "Pyrahist 'C' Cold Capsules," and "Urettes"; and display cards reading in part "Gelatins . . . for Problem Nails."

RESULTS OF INVESTIGATION: Analysis showed that the *Slumba-Rest* contained 88.4 percent of the labeled amount of methapyrilene hydrochloride and that scopolamine aminoxide was detected in such article by qualitative test; the *Nulpain* contained 94.0 percent of the labeled amount of N-acetyl-p-aminophenol; the *Seco-Synatan* contained 88.6 percent of the labeled amount of d-amphetamine tannate and 92.0 percent of the labeled amount of secobarbital sodium; the *Pyrahist "C" Cold capsules* contained approximately 110 percent of the labeled amount of quinine sulfate and 102 percent of the labeled amount of salicylamide but had not been analyzed for their atropine sulfate content which was declared on the label to be 1/600 grain of atropine sulfate per capsule; and the *Urettes* contained 94 percent of the labeled amount of methenamine and 89 percent of the labeled amount of salol.

LIBELED: 9–27–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, (*Slumba-Rest*) the labeling contained false and misleading representations that the article was adequate and effective for relieving nervousness and worry, and as an effective tranquilizer for jittery nerves; (*Nulpain*) the statements on the labeling, "fast pain reliever" and "This chemical goes to work instantly in your body to give you fast relief" were false and misleading; (*Pyrahist "C" Cold capsules*) the statements in the labeling, "Sinus Congestion" and "Gives Immediate relief to Distressing Symptoms of Colds" contained false and misleading representations that the article was adequate and effective as a treatment for sinus congestion and colds; and (*Gelatins*) the labeling contained false and misleading representations that the article was adequate and effective as an aid in the prevention of chipping, breaking, splitting, and peeling of the fingernails when used according to directions; 502(b)(1)—the *Seco-Synatan* failed to bear a label containing the correct name of the repacker, Everglade Drug Co., Inc., Miami, Florida; 502(d)—the *Seco-Synatan* contained secobarbital sodium, a chemical derivative of barbituric acid, and its label failed to bear the name, secobarbital sodium, and quantity or proportion of such substance, and in juxtaposition therewith, the statement "Warning–May be habit forming"; 502(e)(2)—the label of the *Seco-Synatan* failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of the *Seco-Synatan* failed to bear a statement of the common or usual dose; 502(f)(2)—(*Slumba-Rest*) the labeling failed to bear the statement for drugs containing the belladonna derivative, scopolamine, "Warning–Not to be used by persons having glaucoma or excessive pressure within the eye (conditions that occur most often in the elderly), or by children under 12 years of age, unless directed

by physician" and the statement "Caution–Do not exceed recommended dosage. Not for frequent and prolonged use. If dryness of the mouth occurs, decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs."; (*Pyrahist "C" Cold capsules*) the labeling failed to bear the warning statements for drugs containing quinine, antihistaminics, salicylates, and atropine; and (*Nulpain*) the article was offered for the relief of pains of arthritis and rheumatism and its labeling failed to bear the warning statement "Caution–if pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult physician immediately"; and 503(b)(4)—(*Urettes*) the article was a drug subject to the provisions of 503(b)(1) and it failed to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3–19–62. Consent—claimed by Everglade Drug Co., Inc., and released under bond to be brought into compliance with the law.

7073. Phy-Sulfa tablets. (F.D.C. No. 47006. S. No. 46–672 T.)

QUANTITY: 32 1,000-tablet btls. at Herrin, Ill.

SHIPPED: 7–25–61, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Btl.) "Phy-Sulfa Each Tablet Contains: Sulfathiazole 3.75 gr. * * * Distributed by Physicians Supply Co. Herrin, Illinois."

LIBELED: 1–30–62, E. Dist. Ill.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2–27–62. Default—destruction.

7074. Reserpine tablets and folic acid tablets. (F.D.C. No. 46973. S. Nos. 18–033/4 T.)

QUANTITY: 2 499,000-tablet drums of *Reserpine* and 16 1,000-tablet btls. of *folic acid* at Houston, Tex.

SHIPPED: 4–1–60, from Philadelphia, Pa.

LABEL IN PART: (Drum) "No. 1002 * * * Reserpine 0.25 mg. * * * Caution" and (btl.) "1000 Tablets Folic Acid 5 mg. Dosage: One Tablet Three Times Daily."

LIBELED: 2–14–62, S. Dist. Tex.

CHARGE: (*Reserpine tablets*), 501(a)(1)—while held for sale, the article contained moldy tablets; and (*folic acid tablets*), 503(b)(4)—the article was subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 4–6–62. Default—destruction.

7075. Ophthalmic ointment. (F.D.C. No. 46749. S. No. 40–204 T.)

QUANTITY: 56 cases, 24 ⅛-oz. tubes each, at Freeport, N.Y.

SHIPPED: 2–16–61, from Hoboken, N.J., by Morse Laboratories, Inc.

LABEL IN PART: (Ctn. and tube) "Eye-Sty Ophthalmic Ointment For Relief Of Discomfort Caused By Styes and Granulated Eye Lids—Double Antibiotic-Anesthetic Cont. ⅛ Oz. * * * Jabert Pharmacal Co., Inc. Freeport, N.Y., Dist. Contains: Benzocaine 0.5% Mercuric Oxide 1% Boric Acid 5% Tyrothricin 0.01% and Gramacidin 0.0025%."

LIBELED: 12–28–61, E. Dist. N.Y.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3–19–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

7076. Femicin tablets. (F.D.C. No. 43353. S. No. 60–863 P.)

QUANTITY: 84 ctns. at Akron, Ohio.

SHIPPED: 4–1–59, from Thayer Laboratories, Inc., Div. of Revlon, Inc., New York, N.Y.

LABEL IN PART: "Femicin A new scientific compound of potent, prescription-type drugs, specifically formulated * * * Active Ingredients: Each tablet contains: Salicylamide 225 mg., Acetophenetidin 160 mg., Caffeine 65 mg., Pyrilamine Maleate 15 mg., Homatropine Methylbromide 0.5 mg. Contents—16 tablets Thayer Laboratories, Inc., Distr. New York, N.Y."

ACCOMPANYING LABELING: Leaflet in carton reading "Science conquers periodic distress . . ." and display carton reading "Shattered by Periodic Distress? * * * New Medical Discovery 'Femicin'."

LIBELED: 8–21–59, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling of the article contained statements which represented and suggested that the article was an adequate and effective treatment for all emotional and physical discomfort and distress (anxiety, nervous tension, depression, crying, irritability, cramps, headache, muscular pains, bloating, backache, painful breasts, etc.) that may be associated with the menstrual cycle, which statements were false and misleading since the article was not an adequate and effective treatment for such conditions and purposes; and 502(f) (1) and (2)—when shipped, the labeling of the article failed to bear adequate directions for use in that it failed to state that the recommended dosage should not be exceeded and that the article was not for frequent or prolonged use; and its labeling failed to warn that if dryness of the mouth occurred the dosage should be decreased; that if rapid pulse, dizziness, or blurring of vision occurred use of the article should be discontinued; and that the preparation might cause drowsiness and one should not drive or operate machinery while taking the medication.

DISPOSITION: Thayer Laboratories, Inc., Div. of Revlon, Inc., appeared as claimant and filed an answer denying that the article was misbranded. Thereafter, the claimant filed a motion for removal of the case to the Eastern District of New York. Such motion was opposed by the Government and, on 9–1–60, the court handed down the following opinion:

KALBFLEISCH, *District Judge:* "This is an action *in rem* involving the alleged misbranding of an article called 'Femicin.' The libel alleges that the article was misbranded when introduced into and while in interstate commerce, within the meaning of 21 U.S.C.A., 352(a) and 352(f) (1) and (2). The drug was seized in this district under authority of the Food and Drug Act, 21 U.S.C.A., 301, et seq.

*See also Nos. 7062–7064, 7071, 7072.

"The manufacturer and claimant herein, Thayer Laboratories, has its main offices located in the Southern District of New York in the Borough of Manhattan. Pursuant to 21 U.S.C.A., 334(a), claimant has filed a motion for an order removing this cause to the Eastern District of New York for trial. The motion is couched in language as follows:

> Pursuant to 21 U.S.C.A., 334(a), claimant, by and through its attorneys, moves the Court for an order removing this case for trial to the United States District Court for the Eastern District of New York, a district of reasonable proximity to the claimant's principal place of business in the Southern District of New York.

"The portion of the above statute applicable here provides as follows:

> In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

"The parties have at all times been unable to agree and stipulate as to a place for trial and, accordingly, the claimant filed its motion for removal. The Government opposes removal to the district specified in claimant's motion, suggesting instead that the case be transferred to the United States District Court of New Jersey, at Newark. It is contended by the parties that under the statute, sans a stipulation, the claimant has no right to removal of the case to the district of its principal place of business. The Government concedes that claimant has a right to removal to a district of 'reasonable proximity to the claimant's principal place of business.'

"The issue here arises from claimant's contention that it has the right to removal 'to a district specified in its motion' so long as that specified district is of reasonable proximity to but not in the district of its principal place of business. In support of this contention the claimant relies upon the legislative history of the statute. This contention was so vigorously urged in the claimant's brief that the Court yielded to a request for an oral hearing. At the conclusion of the oral hearing it was resolved that the statute is so clear and unambiguous that recourse to the legislative history is unnecessary. Upon direct inquiry by the Court at the oral hearing, claimant's counsel declared that its motion was intended to invoke the provisions of Section 334(a), *supra*.

"There is nothing in the statute which suggests that claimant has the right to choose the judicial district, of reasonable proximity to the claimant's principal place of business, to which a seizure case shall be removed for trial. At this point it is important to note that the Government at no time opposed the removal of this cause from this district. However, the Government opposes the removal to the district specified in claimant's motion and suggests the case be removed to the District of New Jersey, at Newark.

"The statute clearly provides that upon motion of a claimant, the Court, not the parties, shall specify the district of reasonable proximity to claimant's place of business. Under the Act, the power of removal is exclusively conferred upon this Court, barring, of course, the existence of a stipulation of the parties on the subject, *United States* v. *United States District Court for the Eastern District of Arkansas*, et al., 226 F. 2d 238.

"Having declared that this motion is in compliance with Section 334(a), *supra*, and that its purpose is to invoke the provisions of such section, the claimant would limit the Court, in dealing with and disposing of the motion, to the claimant's choice or selection. I cannot agree with the interpretation and contention of the claimant. The character of a motion is determined by the facts stated *and the relief authorized to be granted.*

"Therefore, the Court will order that this case shall be removed for trial to the United States District Court for the District of New Jersey, at Newark, New Jersey."

Pursuant to the foregoing opinion, the court, on 9–6–60, entered an order directing that the case be removed for trial to the District of New Jersey. The claimant filed a motion for reconsideration of the order of removal and, on or about 10–4–60, such motion was overruled by the United States District Court for the Northern District of Ohio. Thereafter, the claimant filed a motion with the United States District Court for the District of New Jersey to remand the case to the Northern District of Ohio which was subsequently denied.

Interrogatories were served upon the claimant by the Government after which the claimant submitted answers to some of the interrogatories and objections to the others. The claimant also served interrogatories upon the Government, following which the Government filed a motion for an order compelling claimant to answer the Government's interrogatories and to stay the time for the Government to object or answer the claimant's interrogatories.

The court, on 3–20–61, after consideration of the briefs and arguments of counsel, entered an order denying the Government's motion for a stay; sustaining claimant's objections to some of the Government's interrogatories; denying claimant's objections to certain other interrogatories; and directing that certain interrogatories be modified.

On 4–19–62, the claimant having filed a motion for leave to withdraw its claim and answer, the court granted the motion and entered an order providing for condemnation and destruction of the article.

7077. Various drugs. (Inj. No. 417.)

COMPLAINT FOR INJUNCTION FILED: 8–31–61, E. Dist. Wis., against Royal Lee, an individual; Vitamin Products Co., a corporation; Lee Foundation for Nutritional Research, a corporation; Endocardiograph Co., Inc.; and Leeland, Inc.; all of Milwaukee, Wis.

CHARGE: The complaint alleged that the defendants were engaged in the business of manufacturing, packing, repacking, labeling, relabeling, promoting, selling, and distributing the following drugs: *Acidophilus Yeast tablets, Lactic Acid Yeast wafers, Catalyn tablets, Cyro-Yeast tablets, Cyroplex wafers, Cataplex A tablets, Vitamin A Complex wafers, Cataplex A & C tablets, Vitamin A & C Complexes wafers, Vitamin A-C-P Complexes wafers, Cataplex A & F with Betaris tablets, Vitamin A & F with Betafood wafers, Cataplex B tablets, Vitamin B Complex wafers, Cataplex C tablets, Vitamin C Complex wafers, Cataplex D tablets, Vitamin D Complex wafers, Cataplex E tablets, Vitamin E Complex wafers, Cataplex F tablets, Vitamin F Complex wafers, Cataplex G tablets, Vitamin G Complex wafers, Phosphade liquid, Phosfood liquid, Phosphade wafers, Phosfood wafers, Phosfood Powder, Cerol Perles, Vitamin E Wheat Germ Oil Perles, Eflex Perles, Vitamin F Oil Perles, Minaplex tablets, Organic Minerals wafers, Ferroplus tablets, Ferrofood wafers, Cerodyn tablets, Cyrofood tablets, Cyrofood D tablets, Calciphade tablets, Calciplex tablets, Calsol wafers, Protedyn capsules, Protefood capsules, Betaris tablets, Betafood wafers, Betalco tablets, Betacol wafers, Rutaplex tablets, Cyruta wafers, Rutaplex A tablets, Cyruta A wafers, Biost tablets, Calcifood A tablets, Eff-Plus tablets, Super-Eff capsules, Cataplex E_2 tablets, Vitamin E_2 wafers, Biost tablets, Ostogen wafers, Adrenamin wafers, Cyrofood tablets, Allorganic Trace Minerals tablets, Anti-Pyrexin wafers, Arginex tablets, Bio-Dent tablets, betaine hydrochloride tablets, Cal-Amo tablets, calcium lactate*

tablets, Carbamide tablets, Aqueous Chlorophyll capsules, Chlorophyll Perles, Fat Soluble Chlorophyll ointment, Cholacol tablets, Choline tablets, Collinsonia capsules, Comfrey, Pepsin & E_3 capsules, Di-Sodium Phosphate tablets, Formula G–E–C tablets, Inositol tablets, Lecithin Perles, Manganese Glycerophosphate tablets, Niacinamide B_6 capsules, Nucleo-Protein capsules, Orchex tablets, Organic Iodine tablets, potassium bicarbonate USP, Prostex tablets, Ribo-Nucleic Acid tablets, sodium citrate tablets, vitamin B_{12} tablets, Vitamin F ointment, Vitamin F liniment, Zymex wafers, Beef Adrenal tablets, Beef Bone (Ostogen) tablets, Beef Brain tablets, Beef Epithelial Tissue tablets, Beef Eye tablets, Beef Heart (Cardiotrophin) tablets, Beef Kidney tablets, Beef Liver tablets, Beef Lung (Pneumotrophin) tablets, Beef Orchic tablets, Beef Ovary tablets, Beef Pancreas tablets, Beef Parotid tablets, Beef Pituitary tablets, Beef Prostate tablets, Beef Spleen tablets, Beef Thymus tablets, Beef Thyroid tablets, Beef Uterus tablets, Beef Mammary tablets, Beef Muscle tablets, and *Bile Salt tablets.*

The complaint alleged further that in the promotion, sale, and distribution of these drugs, defendants employed labels and accompanying labeling including the following written, printed, and graphic matter: booklets entitled, "Schedule of Recommendations for Specific Conditions of Malnutrition . . . Therapeutic Foods Co." and "Schedule of Recommendations for Specific Conditions of Malnutrition . . . Vitamin Products Co."; looseleaf folders entitled, "Therapeutic Food Manual.," "Therapeutic Foods Company . . . Product Information for Doctors.," and "Vitamin Products Company . . . Product Information for Doctors."; booklets entitled, "Standard Process Laboratories . . . Protomorphogens Non-Vitamin Food Factors.," "Applied Trophology . . . 1957, Volume 1, numbers 1–12," and "Applied Trophology . . . 1958, Volume 2, numbers 1–12"; leaflets entitled, "Deficiency Examination Questionnaire." and "How to Use the Deficiency Examination Questionnaire."; booklets entitled, "The Possible Relation of Nutritional Deficiencies to Diabetes.," "Nutrition and Arthritis.," "The Possible Relation of Nutritional Deficiencies to Stomach Ulcers.," "The Possible Relation of Nutritional Deficiencies to Sex Disorders.," "Applied Protomorphology.," "Issues on Relations of Vitamins to Heart Disease.," "The Possible Relation of Nutritional Deficiencies to Prostatic Hypertrophy.," and "Applied Physiology of the Adrenal Glands."; looseleaf booklet entitled, "Vitamin News."; looseleaf folder entitled, "Clinical Coordination Manual Product Bulletin . . . Therapeutic Foods Company."; pamphlet entitled, "Suggestions for Taking Supplements and Reactions that Might Occur."; booklet entitled, "A Survey of Vitamin F."; looseleaf folder entitled, "Therapeutic Foods Company . . . Doctors Books An Introduction to Clinical Nutrition."; booklet entitled, "Endocardiograph Operation Interpretations and Suggested Therapeutic Measures . . . Endo Cardiograph Company, Milwaukee."; looseleaf folder entitled, "Cytrophic Extracts – Standard Process Laboratories, Milwaukee 3, Wisconsin."; booklet entitled, "Anti-Gastrin . . . Standard Process Laboratories, Milwaukee, Wisconsin."; double-pocket folder entitled, "Introduction to Natural Vitamins (for the Dental Profession) . . . Vitamin Products Company" containing: booklets entitled, "Joan" by Fred D. Miller, D.D.S., "Schedule of Recommendations for Specific Conditions of Malnutrition.," "Introducing . . . Vitamins with their Natural Synergists.," "Our Teeth and our Soils" by William A. Albrecht, and "Case of Dental Caries vs. the Sugar Interests."; leaflets entitled, "Nutrition and Dental Disease" by Allison G. James, D.D.S., "What Is A Vitamin?," "Clinical Nutrition (– Foods vs. Drugs –)," and "The Fallacy of 'High Potency' in Vitamin Dosage."; booklets

entitled, "Calcium" by William A. Albrecht . . . Reprint No. 8, Lee Foundation for Nutritional Research., "How Our Government Subsidizes Malnutrition and Disease . . . Special Bulletin 1–49, Lee Foundation for Nutritional Research.," and "Fundamentals of Nutrition for Physicians and Dentists . . . Reprint No. 33, Lee Foundation for Nutritional Research."; leaflet entitled, "Reprint No. 49–A Lee Foundation for Nutritional Research, Milwaukee, Wisconsin Proceedings . . . The Well-Fed Tooth."; booklets entitled, "A Practical Way to Avoid Malnutrition . . . Lee Foundation for Nutritional Research." and "Some Phases of Our Many-Sided Denture Problem."; leaflets entitled, "Biost V–P 730.," "The Importance of Food Enzymes in Promoting Mineral Assimilation.," "Calcium Types in Dentistry . . . Lee Foundation for Nutritional Research.," "Experiences of One Dentist With V–P Products.," and "For Physicians Only CHLOROPHYLL—Physiological Effects."; order forms of Vitamin Products Co., Therapeutic Foods Co., and Standard Process Laboratories.; double-pocket folder entitled, "Introduction to Natural Vitamins . . . Vitamin Products Co." containing: booklet entitled, "A Practical Way to Avoid Malnutrition . . . Lee Foundation for Nutritional Research."; leaflet entitled, "Acid or Alkaline Diet Control."; cards entitled, "Cancer – Nutritional Factors In.," "Cardiovascular Disease and Malnutrition.," and "Fatigue and Malnutrition Syndrome."; booklets entitled, "Introducing . . . Vitamins with their Natural Synergists." and "Catalogue and Price List . . . Standard Process Laboratories."; leaflets entitled, "Deficiency Examination Questionnaire.," "How to Use the Deficiency Examination Questionnaire.," and "For Physicians Only CHLOROPHYLL—Physiological Effects."; booklets entitled, "Vitamin F in the Treatment of Prostatic Hypertrophy . . . Lee Foundation for Nutritional Research.," "Practical Aspects of Applied Nutrition . . . Reprint No. 61, Lee Foundation for Nutritional Research.," "The Special Nutritional Qualities of Natural Foods . . . Lee Foundation for Nutritional Research.," "How and Why Synthetic Poisons are Being Sold as Imitations of Natural Foods and Drugs . . . Lee Foundation for Nutritional Research.," "The Effect of Aluminum Compounds in Foods . . . Lee Foundation for Nutritional Research.," "How Our Government Subsidizes Malnutrition and Disease . . . Special Bulletin 1–49, Lee Foundation for Nutritional Research.," and "A Discussion of the Forms of Blood Calcium . . . Lee Foundation for Nutritional Research."; leaflets entitled, "Some Interrelations Between Vitamins and Hormones.," "Clinical Nutrition (– Foods vs. Drugs –).," "The Fallacy of 'High Potency' in Vitamin Dosage.," "Information on Products Manufactured by The Vitamin Products Company.," "Cardiotrophin A Heart Protomorphogen.," "Pneumotrophin.," "Anti – Pyrexin.," "Zymex.," "Cataplex A & F with Betaris.," "Rutaplex A.," "Cerol.," "Biost.," "Cataplex E_2.," and "The Importance of Food Enzymes in Promoting Mineral Assimilation."; order forms of Standard Process Laboratories and Vitamin Products Co.; looseleaf folders entitled, "Portfolio of Reprints for the Doctor . . . Lee Foundation for Nutritional Research." and "Portfolio of Reprints for the Layman and Housewife . . . Lee Foundation for Nutritional Research."; booklets entitled, "Applied Trophology . . . Vol. 3, January–December 1959, monthly issues.," "Applied Trophology . . . Vol. 4, January – December 1960, monthly issues.," and "Applied Trophology . . . Vol. 5, January – July 1961, monthly issues."; looseleaf folder entitled, "Portfolio of Reprints for the Agriculturist * * * Lee Foundation for Nutritional Research Milwaukee 3, Wisconsin"; leaflet entitled, in part, "Catalyn * * * Vitamin Products Company Milwaukee 3, Wisconsin."; looseleaf folder entitled, in part, "Syncrinology * * *"; loose-

leaf folder entitled, "The Possible Relation of Nutritional Deficiencies to Dental Disease"; leaflet entitled, in part, "Cardiotrophin * * * Standard Process Laboratories – Milwaukee 1, Wisconsin"; looseleaf folder entitled "Poliomyelitis"; looseleaf folder with no title—first page starts, "Clinical Appraisal Report"; looseleaf folder entitled, "Portfolio of Reprints for the Housewife * * * Lee Foundation for Nutritional Research"; and other similar written, printed, and graphic material.

The complaint alleged further that in carrying on the business of distributing these drugs and labeling, the defendants employed essentially the following methods of operation:

Various quantities of the drugs and labeling were shipped by the defendants from time to time, from Milwaukee, Wis., to defendants' employees, agents, servants, representatives, franchise holders, and distributors located in many major cities in the United States, who, in turn, at defendants' direction, promoted defendants' products to various medical and general practitioners, and to the general public, by use of the described labeling and by other means, and distributed and sold defendants' products to such practitioners and to the general public. Some pieces of the labeling were also mailed direct, by the defendants, from Milwaukee, Wis., to various practitioners of the medical and dental professions throughout the United States, together with order forms for the drugs; and the drugs were subsequently shipped, by the defendants, from Milwaukee, Wis., direct to those practitioners who executed and sent in order forms to the defendants.

The complaint alleged further that the drugs were misbranded under 502(a) in that their labeling falsely represented and suggested that the drugs, simply or in combination, were an adequate and effective treatment for one or more of the following symptoms, diseases, and conditions: acid urine, ascites, arteriosclerosis, adrenal insufficiency, anoxia, anorexia, adrenal dysfunction, asthma allergic states, alkalosis, acidosis, acute indigestion, allergies, aging process, achlorhydria, autonomic unbalance, amenorrhea, abortion, angina pectoris, acne vulgaris, anemia, asthenia, arcus senilis, albuminuria, alcoholism, adiposity, asthenic behavior, absence of hair growth, angelic tendency, anxiety, atonic constipation, atonic sphincters, Anders' disease, bursitis, bronchitis, burning skin, blood sludge "thickening", breathlessness, blood pressure changes, boils, burns, Buerger's disease, brucellosis, biliary stasis, backward children, brain concussion, brain dysfunction, bradycardia, bed sores, bloody stool, blurred vision, body odor, bone regeneration, brittle nails, burning sensations on feet, bone fracture repair, boggy uterus, "crawling" sensations of the skin, calcium therapy, cheilosis, chronic cough, cystitis, "cold-sweat" type perspiration, calcium deficiency symptoms, circulatory disturbances, coronary sclerosis, chronic indigestion, constipation, chronic diseases, cancer, cramps, congenital weakness, craving for acids, colds, caries, cataracts, conjunctivitis, cerebral palsy, cold hands and feet, chorea, cardiac arrhythmia, cholesterol, cardiac edema, cerebral hemorrhage, children's infectious diseases, chicken pox, cirrhosis of the liver, convulsions in infants, coronary insufficiency, craving for salt, chronic hypertrophy of tonsils and adenoids, congenital anemia, craving for alcohol, collagen diseases, controlling edema, combatting capillary engorgement, cigarette cough, carbuncles, cretins, dislike for closed rooms, dysmenorrhea, diarrhea, decreased appetite, dry skin, deficient intake of acid-ash foods, dysphagia, dryness of mouth, dry, hard stool, diminished urination, diminished perspiration, dizziness, drowsiness, dermatitis, diabetes, diarrhea of infants, dropsy, deafness, denture irritation, delirium, disc lesions,

Dupuytren's contracture, deformity of ligaments, dehydration, dullness, darkened skin, difficult perspiration, difficult swallowing, dry mouth with thick, ropey saliva, decreased blood sugar, decreased cholesterol, decreased blood calcium, decreased carbohydrate tolerance, diabetic retinitis, duodenal ulcer, dementia praecox, enzymatic tranquilizing, emphysema, edema of ankles, easily formed "goose flesh", excessive intake of carbohydrates, excessive alkaline-ash foods, endocrine insufficiency, eating when not hungry, emaciation, edema, epistaxis, excessive appetite, earache, endocervicitis, epilepsy, eye conditions, eczema, excessive hair growth, early dentition, excessive perspiration, early appearance of pubic hair, early menstruation, exophthalmos, extreme response to stress, edema of the lids, eyebrows meeting in center, excess watery saliva, extra systoles, endometritis, encephalomyelitic paralysis, exophthalmic goiter, fullness after meals, fatigue, faulty digestion, fluid loss, feeling worse after eating, fevers, frequent sighing, failure of adrenal mechanisms caused by excessive mental stress or shock, "flu", fibroid tumors, febrile diseases, flatulence, fair skin, frequent winking and blinking of the eyes, fibrillations of the heart, fibrositis, gingivitis, glossitis, gallbladder dysfunction, glandular disorders, gastric hyperacidity, grippe, gout, gastric ulcer, goiter, gynecomastia, "goose flesh" not easily formed, glaucoma, gallbladder inflammation, gallstones, gastritis, gingival bleeding, glomerulonephritis, hypochlorhydria, hydrochloric loss from longstanding hyperacidity, hypertrophic arthritis, halitosis, hyperirritability, hypercholesterolemia, heavy, slow pulse, hypertension, high-altitude discomfort, hay fever, heart abnormalities, herpes simplex, histamine reactions, hives, hypocholesterolemia, hypotension, heat prostration, hemorrhoids, hernia, hepatitis, herpes zoster, headaches, hypoglycemia, high-pitched voice, high blood pressure, hyperdevelopment, heavy-toned voice, heavy and coarse axillary and pubic hair, heavy growth on legs and chest, hypoactivity of the adrenals, heart block, hypertrophy of heart, high sedimentation rate, hemolytic anemia, irregular respiration, inability to metabolize carbohydrates, itching skin, insomnia, irritation to inflamed stomach mucosa, increased metabolic requirements, infections, intermittent claudications, intestinal worms, increased urination, impaired vision, increased metabolic rate, increased hair growth, irregular menstruation, immature mammary glands, increased strength in women, irregularities of the teeth, increased tears, increased flow of bile, increased flow of pancreatic juice, increased blood sugar, increased cholesterol, increased blood calcium, increased body weight with low body temperature, increased carbohydrate tolerance, increased appetite, intestinal cramps, irritation to the eye, infectious hepatitis, impotency, intestinal stasis, irritable disposition, infantilism, improving tissue tone, jaundice, kidney stones, ketosis, kidney overload, keloids, liver disease, liver insufficiency, loss of taste for meat, lower bowel gas, leg ulcers, lumbago, leukopenia, lymph node infection, leucorrhea, lowered metabolic rate, lack of hair growth, long eyelashes, low stress tolerance, loss of control of voice, lowered sexual activity and power, large sexual organs, large breasts and clitoris, leucocytosis, laryngitis, loss of taste and smell, liver cirrhosis, lymphatism, metabolic diseases, mental stress, mastitis, mouth and tongue disorders, menopausal disorders, menopausal symptoms, menstrual dysfunction, menstruation symptoms, muscular tremors, migraine headaches, myocarditis, multiple sclerosis, mucous colitis, mental dullness, muscular dystrophy, marked pigmentation of skin, marked gagging reflex, measles, mumps, muscular cramps, malaria, Meniere's disease, mental depression, mitral stenosis, muscular weakness, myasthenia gravis, melancholia, mental retardation, male sterility, mongoloids, milk intolerance, night-

mares, neuralgia, night cough, night cramps, nervous tension due to hydrochloric loss, neurasthenia, nephritis, nausea of pregnancy, neuromuscular disorders, nervous strain, numbness, night blindness, neurodermatitis, nose polyps, numbness from poor circulation, nymphomania, obesity, osteoarthritis, oily skin, osteoporosis, ovarian tumors, pernicious anemia, promoting muscle tone, preventing eclampsia, pregnancy, pallor, protein metabolism, prostatitis, photophobia, peridontoclasia, poison ivy and oak, pruritus, purpura, perspiration, promotion of healing, pain, psoriasis, pneumonia, phlebitis, preserving integrity of nails, pellagra, Peyronie's disease, prostate disease, pruritus vulvae, pruritus ani, palsy, pigmentation of skin, palpitation, precocious development, precocity, poor nervous stamina, puffiness, pale, undernourished mucous membrane, precocious sexual development and desire, pain in bones, Paget's disease, painful breasts, paralysis agitans, Parkinson's disease, pyorrhea, poliomyelitis, polpus recta, poor memory, prostate hypertrophy, paroxysmal tachycardia, prolapsed uterus, paresis, paroxysmal hemoglobinuria, pulmonary hypertension, pituitary overactivity of male climacteric, peptic ulcer, reducing tissue oxidation rate, relief of pain in cancer, renal calculi, rapid blood-clotting time, reactions to foods, recovery from stroke, rheumatoid arthritis, receding gums, rheumatic fever, respiratory embarrassment, reduced lachrymal secretion, rapid shallow respiration, reduced flow of bile, reduced flow of pancreatic juice, rapid digestion with hunger pains, recurrent fevers, Raynaud's disease, restlessness, skin irritation, sinusitis, sciatica, salivary disorders, starvation, systemic hyperacidity, stiffness of joints, secondary anemia, sterility, systemic toxicity, sneezing attacks, strictures, shock, specific deficiency reactions of glandular conditions, sluggish mentality, sexual precocity, smooth thin skin, short stature, severe instability, stenosis, sluggish gagging reflex, spastic constipation, spastic sphincter, sparse growth of axillary and pubic hair, slow blood clotting, slow digestion with sour stomach and fermentation, stiff neck, scarlet fever, simple goiter, streptococcus infections, staphylococcus infections, skin itching, stiffness of jaw muscles, sweat gland inactivity, sunstroke, sympathetic ophthalmia, schizophrenia, styes, tachycardia, toxemia, telangiectasis, tinnitus aurium, torticollis, tonsillitis, teething in children, thickened nose, lips, and tongue, tremors, tendency to sweating, thick heavy eyebrows, thin outer ⅓ of eyebrows, thick, infiltrated, dry, rough, and wrinkled skin, toxic goiter, tuberculosis, uremia, urinary incompetence, ulcerative colitis, uterine congestion, underdeveloped sexual organs, uterine cramps, undulant fever, underdeveloped children, voice affected during stress, vomiting, vasomotor involvements, varicose veins, Vincent's infection, virus infections, vaginitis, warts, weakness of legs, white skin, weight gain, weight loss, well-developed hair growth, and X-ray burns.

It was alleged further that the drugs were misbranded under 502(a) in that their labeling contained false and misleading representations that the drugs were necessary and essential adjuncts to the diet because: all disease conditions are the result of malnutrition; the American diet is "terribly deficient" in essential vitamins and minerals; practically everyone in this country is suffering from, or is in danger of suffering from, a serious dietary deficiency of vitamins and minerals due to foods being grown on depleted soils and due to pasteurization, storage, canning, processing, refining, shipping, freezing, and cooking of foods; medical men should cure disease by use of foods and food supplements rather than by use of drugs; practically the whole array of chronic and acute diseases may in some degree be related to acid-base disorders which should be treated by use of the defendants' products; a positive

relationship between heart disease and malnutrition has now been firmly established; as a nation we are starving to death in the presence of medical men who know more about poisons than they do about food and who think first of what poison to use instead of what food to use when confronted by a therapeutic problem; the leading cause of death in America is heart disease which is caused by nutritional deficiencies; 700,000 people a year die of preventable and curable heart disease caused by deficiency of natural vitamins; dental caries are due to a diet deficient in natural vitamins; the value of antigenic extracts of specific organs (cytotropic extracts) is of unquestionable value in restoring health to the target organ; arthritis and tooth decay are caused by the eating of cooked food; polio is a degenerative disease caused by the eating of overcooked and refined foods; and that each of the drugs contains "unknown factors" of therapeutic value.

The drugs were alleged further to be misbranded under 502(f)(1) in that their labeling failed to bear adequate directions for use in the treatment of the symptoms, diseases, and conditions for which they were claimed to be effective.

Further allegations of the complaint charged the defendants with violating the Act by introducing and delivering for introduction into interstate commerce, misbranded drugs; by receiving and causing to be received in interstate commerce, misbranded drugs; by delivering and proffering for delivery, misbranded drugs, for pay or otherwise; and by causing the drugs to be accompanied by the above-mentioned labeling, while held for sale after shipment in interstate commerce, which act resulted in the drugs being misbranded.

DISPOSITION: On 1–15–62, the defendants having consented to entry of a decree, the court entered a decree of permanent injunction enjoining the defendants from directly or indirectly introducing or delivering for introduction into interstate commerce, the drugs referred to in the complaint, or the same drugs by any other designation, or any other drugs which are accompanied by the labeling described in the complaint or accompanied by other written, printed, or graphic matter containing the false and misleading representations alleged in the complaint or any similar false and misleading representations; or which fail to bear in their labeling a statement of all conditions and purposes for which such drugs are intended to be used and sufficient information to enable a layman to safely and efficaciously use such drugs for such purposes. The decree also enjoined the defendants (1) from receiving in interstate commerce such drugs in a misbranded condition and delivering such drugs, or proffering them for delivery, for pay or otherwise, and (2) from doing any act with respect to such drugs, while they are held for sale by the defendants after shipment in interstate commerce, which will result in the drugs being misbranded.

The decree further enjoined the defendants from directly or indirectly introducing or delivering for introduction into interstate commerce, any of the drugs designated in the complaint, or the same drugs by any other designation, or any other drug, to any person who has in his possession any written, printed, or graphic matter as specified in the complaint, or similar thereto.

The decree also enjoined defendants from writing, printing, or distributing any of the specified written, printed, or graphic matter, or any other written, printed, or graphic matter, which contains any statements that represent or suggest that any of the drugs named in the complaint, or the same drugs by any other designation, or any other drugs, are adequate and effective for the treatment, mitigation, cure, or prevention of any of the symptoms, diseases, or conditions specified in the complaint, or any other symptom, disease, or

conditions; or which makes any of the other representations specified in the complaint or any similar representations.

7078. Nutri-Bio food supplement. (F.D.C. No. 47370. S. Nos. 51–416 T, 52–770 T, 53–103 T.)

QUANTITY: 64 ctns. at Seattle, Wash.

SHIPPED: Between 11–20–61 and 12–8–61, from Beverly Hills, Calif., by Nutri-Bio Corp.

LABEL IN PART: (Ctn.) "Nutri-Bio dietary food supplements * * * Formulated for and Distributed by Nutri-Bio Corporation * * * Beverly Hills, Calif. Available only through Authorized Nutri-Bio Distributors" and "Vitamins and Minerals from natural food sources * * * 728 Mineral Tablets 364 Vitamin Tablets."

ACCOMPANYING LABELING: Bound volume and single issues of "Nutri-Bio News" for Nov. 1958–Oct. 1959, 1960, and 1961; Nutri-Bio Sales Manuals; reprints designated, "San Jose State College Track Coach/Nutri-Bio letter July 31, 1958," "Great Falls Electric letter with enclosure June 25, 1958," "Rex Johnston/Nutri-Bio letter August 9, 1958," "San Jose State College Boxing Coach/Nutri-Bio letter July 31, 1958," "More Athletes on Nutri-Bio," "Southern Association Vitamins Help," 1957 issue of "Specialty-Salesman," and May 25, 1959 issue of "Life"; pamphlets entitled, "For More Radiant Living," "Why a Food Supplement," "How to get started in Nutri-Bio," "Food Supplement-Protein," "How Much Health Did You Buy Today," "Protein Recipes," "What is the Secret of Our Success," "The Nutri-Bio Open Door," and "A Nutri-Bio Discount Schedule"; leaflets entitled, "Let's Take a Peek," "The Nutri-Bio Program For Better Living," "Do You Know," and "Vitamin and Mineral Food Supplement"; film strips entitled, "You and Your Future With Nutri-Bio," "Give Yourself a Break," and "Just To be Sure"; records entitled, "Take Care of Yourself For Me," "You and Your Future With Nutri-Bio," "Give Yourself a Break," and "Just To Be Sure"; Basic Food Charts; Basic Charts Balanced Nutrition; post cards, "Better Nutrition Through Bio-Chemistry"; and Starting Kits.

LIBELED: 3–12–62, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective to prevent loss of appetite, constipation, hemorrhage of mucous membranes, palpitation of the heart, nervousness, excess bleeding, rundown feeling, toxic elements in the digestive system, to promote resistance to infections, stamina and endurance, quicker reflexes, mental alertness, strength, growth, radiant living, general well-being, athletic ability, added energy, increased physical endurance, and zest for living; that everyone needs food supplements; that the articles were of special significance for special dietary supplementation and therapeutic use because the ingredients were of natural or organic origin; and that the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, choline, alfalfa juice and powder concentrate, potassium, sulfur, copper, zinc, manganese, magnesium, and montmorillonite; and 502(f)(1)—the labeling failed to bear adequate directions for use in the treatment and prevention of dental caries, anemia, colds, "flu," arthritis, restlessness, insomnia, heart disease, increased blood

cholesterol, and pimples; to build up the body; build up the blood; to rebuild tissues that have been broken down by cancer and to keep cancer from spreading, which were the conditions and purposes for which the articles were offered and intended, in oral statements, made by Mr. and Mrs. Alf Kvinge, who were Nutri-Bio distributors.

DISPOSITION: 4–23–62. Default—destruction.

7079. Nutri-Bio food supplement. (F.D.C. No. 47188. S. Nos. 10–076/7 T, 10–670 T.)

QUANTITY: 31 units, each consisting of 2 ctns. enclosed in a cardboard sleeve, each ctn. containing 13 envelopes of 14 yellow tablets and 28 green tablets each, at Buffalo, N.Y.

SHIPPED: 11–27–61, from Elk Grove Village, Ill., by Nutri-Bio Corp.

LABEL IN PART: (Ctn.) "Nutri-Bio * * * Dietary Food Supplement Vitamin and Mineral Tablets 364 Mineral Tablets 182 Vitamin Tablets * * * Available only through Authorized Nutri-Bio Distributors * * * Formulated for and Distributed by Nutri-Bio Corporation, 291 S. La Cienega Blvd. Beverly Hills, California"; (sleeve) "Nutri-Bio Dietary Food supplement * * * The Nutri Pak * * * Pocket Carriers * * * Contains a 7-Day Adult Supply of Nutri-Bio. This Package contains 26 Nutri-Paks. * * * Nutri-Bio Corporation"; and (envelope) "Your Seven Day Supply of Nutri-Bio Dietary Food Supplement Natural or Organic Vitamins and Minerals for the Entire Family. Formulated for and Distributed by Nutri-Bio."

ACCOMPANYING LABELING: Folders entitled, "Do You Know . . .," "The Nutri-Bio Program For Better Living," and "Baby-Bio by Nutri-Bio"; and booklets entitled, "Why A Food Supplement."

LIBELED: 3–6–62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective to promote being alert, pleasant, calm, and vibrant; to feel well, and to have a zest for living; promote mental and physical health, happiness, sociability, enthusiasm, liveliness, vigor, and awareness; and that the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, chlorine, alfalfa juice and powder concentrate, potassium, sulfur, copper, zinc, manganese, magnesium, and montmorillonite; that every one needs food supplements; and that the article was of special significance for special dietary supplementation and therapeutic use because the ingredients were of natural or organic origin; and 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment and prevention of hemorrhage of the eyes, diabetes, high blood pressure, arthritis, and bursitis, which were the conditions and purposes for which the article was intended and offered, in oral statements, by Ralph Tatro, sales agent for the Nutri-Bio Corp.

DISPOSITION: 4–17–62. Default—destruction.

7080. Special dietary foods. (F.D.C. No. 46032. S. Nos. 85–361/3 R.)

QUANTITY: 145 300-tablet btls. of *Foenugreek tablets;* 10 cases, 12 1-lb. bags each, of *fenugreek seeds;* 118 300-tablet btls. of *mangrove tablets,* at Tulsa, Okla.

SHIPPED: Between 9–22–60 and 4–5–61, from Boulder, Colo., by L. Washburn, Inc.

LABEL IN PART: (Btl.) "Foenugreek Tablets * * * L. Washburn, Inc. Boulder, Colorado Tablets are made of finely powdered, raw, imported Foenugreek seed with edible bone meal added as binder"; (bag) "Washburn's Imported Fenugreek Seeds"; (btl.) "Washburn's Dehydrated Mangrove Leaf in tablets * * * 300 7.7 Grain (½ gram) Tablets * * * made from pulverized, dehydrated Mangrove Leaves and Bone Meal added as binder."

LIBELED: 6–27–61, N. Dist. Okla.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use to (*mangrove tablets*) cleanse and energize the system and to control weight; and (*Foenugreek tablets* and *fenugreek seed*) to dissolve excess mucous; cleanse kidneys, gallbladder, liver, and blood stream; to cleanse and energize the system; control weight; hasten healing of skin wounds and irritations; reduce fevers; and in the treatment of inflamed mucous tissues in colds, diarrhea, and prostate infections.

The articles, together with certain other articles, were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: L. Washburn, Inc., intervened and filed claim to the articles. On 7–26–61, the court ordered the case transferred to the District of Wyoming. Claimant, without admitting the allegations in the libel, consented to a decree, and the court entered a decree of condemnation on 9–29–61, and ordered the articles released under bond to be brought into compliance with the law. The claimant failed to repossess the articles and, on 4–25–62, the court ordered that the articles be destroyed.

7081. **Anti-Chole.** (F.D.C. No. 44572. S. No. 32–768 R.)

QUANTITY: 72 16-oz. btls. at New York, N.Y.

SHIPPED: 4–19–60, from South Hackensack, N.J., by Schiff Bio-Food Products, Inc.

LABEL IN PART: (Btl.) "Anti-Chole A Supplement to Low Cholesterol Diets One tablespoonful (15 grams) per day provides: Unsaturated Fatty Acids–12.5 Gm. or 12,500 mg. Principally as Linoleic Acid together with Linolenic and other essential unsaturated fatty acids as they occur in Safflower and other specially selected vegetable oils * * * Anti-Chole is a palatable preparation derived from the following: Safflower Seed, Sesame, Soy, Soy Lecithin, Rice Germ and Wheat Germ Oils with added mixed tocopherols * * * Formulated & Distr. By Schiff, South Hackensack, New Jersey."

LIBELED: 5–17–60, S. Dist. N.Y.; amended libel 5–8–61.

CHARGE: 502(a)—when shipped, the name of the article, "*Anti-Chole*," and other statements on the bottle label contained false and misleading representations that the article was adequate and effective to regulate and lower the cholesterol of the blood and prevent and treat heart and artery diseases; and 502(f)(1)—its labeling failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: Schiff Bio-Food Products, Inc., claimant, filed an answer denying that the article was misbranded and offering an affirmative defense. On 6–5–62, the claimant having consented to a decree without admitting allega-

tions of the libel, a decree of condemnation was entered and the article was destroyed.

7082. Vegetable juices. (F.D.C. No. 47386. S. No. 32–461 T.)

QUANTITY: 1,420 1-pt. 3-oz. btls. of *carrot juice* and 1,052 1-pt. 3-oz. btls. of *beet juice* at Los Angeles, Calif., in possession of Kahan & Lessin.

SHIPPED: 12–15–60 and 1–15–61, from Seattle, Wash.

LABEL IN PART: (Btl.) "Biotta Lacto-Carrot [or "Lacto-Beet"] Brand Pure Carrot Juice [or "Beet Juice"] bottled with Dr. F. Keitel's Lacto Fermentation Method."

ACCOMPANYING LABELING: Reprints from "Let's Live" magazine entitled, "The Benefits Obtainable from Lacto-Fermented Vegetable Juices, by Dr. Fritz Caspari" and "Lactic Acid Fermented Diet, by E. L. David"; and posters entitled, "Made from Organically Grown Vegetables" and "Biotta Juices 15¢ a Day."

LIBELED: 3–19–62, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of fatigue, obstipation, chronic disturbance of the gastrointestinal tract, unspecified dermatoses, nervous and overstrained conditions, obesity, stomach, liver, and gallbladder conditions, anemia, improper blood pressure, rheumatism, cardiac conditions, cancer, lung cancer, and chronic and infectious diseases; and 502(f)(1)—the labeling failed to bear adequate directions for use in the treatment and prevention of chronic and infectious diseases, stomach, gallbladder, and liver trouble, cancer, fatigue, obstipation, obesity, nervous and overstrained conditions, chronic disturbances of the gastrointestinal tract, unspecified dermatoses, anemia, improper blood pressure, rheumatism, and cardiac conditions, which were the diseases, conditions and purposes for which the articles were intended and for which they had been described, recommended and suggested in the labeling.

DISPOSITION: 6–14–62. Default—delivered to a charitable institution.

7083. Nutri-Seal Admix. (F.D.C. No. 44689. S. No. 43–563 R.)

QUANTITY: 54 cases, each containing 4 1-gal. btls. of *Nutri-Seal Admix*, at Caldwell, Idaho; and 10 1-gal. btls. of *Nutri-Seal Admix* and 1,160 ½-gal. ctns. of a 2 percent skim milk product containing *Nutri-Seal Admix* at Boise and Nampa, Idaho, in possession of Home Dairies Co.

SHIPPED: Between 9–8–59 and 6–21–60, from Los Angeles, Calif., by Nutri-Seal Corp.

LABEL IN PART: (Btl.) "Net Contents 128 Fluid Ounces 9–Vitamin Concentrate Nutri-Seal Admix, Nutri-Seal Corporation, * * * Los Angeles 19, California" and (ctn. of the 2 percent skim milk product containing the Admix) "Home Dairies Enriched Fortified 2% Lo-Fat with Nutri-Seal 9–Vitamins * * * Grade 'A' Fortified and Enriched Skim Milk."

ACCOMPANYING LABELING: Folders reading, in part, "Home Dairies, Nature's Finest, Most Complete Food" and "Home Dairies Enthusiastically Announces"; and 24 cases, each containing 300 empty ½-gal. cartons which bore labels that were the same as the label on the above-described cartons.

RESULTS OF INVESTIGATION: The accompanying labeling had been printed for Home Dairies Co., and was used in promoting sales of the 2 percent skim milk product containing the *Nutri-Seal Admix*.

All of the *Nutri-Seal Admix* had been shipped to Caldwell, Idaho, consigned to the shipper, Nutri-Seal Corp. Some of the *Admix* had been distributed to Home Dairies Co., after which a portion was incorporated into the 2 percent skim milk product.

LIBELED: 7–1–60, Dist. Idaho; amended libel on or about 11–28–61.

CHARGE: 502(a)—while held for sale, the labeling of the *Nutri-Seal Admix* at Boise and Nampa, Idaho, both before and after the *Admix* was mixed with the 2 percent skim milk product, contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of ailments; and 502(f)(1)—when shipped, the labeling of the *Admix* at Caldwell, Idaho failed to bear adequate directions for the treatment and prevention of the conditions for which it was intended, namely, weakness, anemia, spongy gums, skin hemorrhages, disorders of the skin, eyes, and nervous tissue, skin irritations, loss of appetite, fatigue, and to maintain normal skin resistance to infection; and to promote development of tooth enamel, good vision, and formation of normal bones and teeth; effect normal reproduction; maintain normal muscle tone, normal digestion and gastrointestinal tonus; produce growth, fertility, lactation, and normal functioning of the nervous tissue; produce antibodies; and develop a normal central nervous system.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 12–2–60, a default decree of condemnation was entered against the 1-gal. bottles of *Nutri-Seal Admix* and ½-gal. cartons of the 2 percent skim milk product containing the *Admix* which were in possession of Home Dairies Co., at Boise and Nampa, Idaho. The decree provided that such articles should be destroyed except for 4 1-gal. bottles of the *Admix*, 25 empty ½-gal. cartons of 2 percent skim milk product, and a number of folders which should be delivered to the Food and Drug Administration.

On 3–27–61, Home Dairies Co. having filed claim for the empty ½-gal. milk cartons, a decree amending the decree of 12–6–60 was entered providing for the release, under bond, of the cartons for purpose of salvage.

On 11–30–61, Nutri-Seal Corp., claimant for the 54 cases of *Nutri-Seal Admix* at Caldwell, Idaho, having denied that the article was misbranded as alleged in the original libel but not denying that the labeling contained statements that the article was suitable as an addition to cottage cheese as alleged in the amendment to the libel and having consented to the entry of the decree, judgment of condemnation was entered and the article was ordered released, under bond, for relabeling in compliance with the law. On 6–22–62, the claimant having decided not to relabel the article and agreeing to its disposition within the discretion of the court, an order was entered for destruction of the article.

7084. Antiseptic mouthwash. (F.D.C. No. 47197. S. No. 47–780 T.)

QUANTITY: 25 cases, 24 units each, consisting of 1 14-oz. btl. and 1 6-oz. btl. each, at Memphis, Tenn.

SHIPPED: 12–6–61, from St. Louis, Mo., by Vi-Jon Laboratories, Inc.

LABEL IN PART: (Case) "24 combination deals Vi-Jon St. Louis, Mo. Antiseptic Mouth Wash"; (btl.) "Hospital Brand Vi-Jon Antiseptic Mouthwash

* * * Active Ingredients 25% Alcohol, Eucalyptol, Thymol, Menthol, Methyl Salicylate, Benzoic Acid, Boric Acid * * * Vi-Jon Laboratories, Inc."; and (strip label) "Free 6 oz. Size With Purchase of Family Size * * * Vi-Jon Laboratories, Inc."

RESULTS OF INVESTIGATION: Examination of the retail unit showed that the 6-oz. and 14-oz. bottles were fastened together side by side, by means of a paper tape extending around the base of both bottles. This paper tape completely covered the statement of active ingredients, partly covered the statement of conditions for use on the label of the 14-oz. bottle, and completely covered or obscured the statement of active ingredients and statement of conditions for use on the 6-oz. bottle label, both by physical contact of the tape with the printed matter and by the manner in which the label of the 6-oz. bottle was held against the 14-oz. bottle label. The quantity of contents statement of the 6-oz. bottle was printed in very small type, making the figure "6" appear to be an "8." The quantity of contents statement of the 14-oz. bottle, and the name and place of business of the manufacturer and directions for use on both labels, were printed on the inside of the label and could be seen only with great difficulty, since they were obscured by the tape covering the 6-oz. bottle and by the 6-oz. bottle itself in the case of the 14-oz. bottle. The printed matter obscured by direct contact with the tape was lost when the tape was removed because it stuck to the gummed side of the tape.

LIBELED: 3–8–62, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective as a treatment for colds and sore throats, and that holding the article in the mouth for a moment would kill many germs that cause infection; the label statement "Kills germs in half the time required by U.S. Government tests" was false and misleading, since there is no such U.S. Government requirement; 502(c)—the information required to appear on the label or in the labeling under 502(b)(1), the name and place of business of the manufacturer, packer, or distributor, 502(b)(2), an accurate statement of the quantity of contents, 502(e)(2), the common or usual name of each active ingredient, and 502(f)(1), adequate directions for use, was not prominently placed on the label with such conspicuousness (as compared with other words and statements on the label) as to render such information likely to be read by the ordinary individual under customary conditions of purchase and use; and 502(f)(2)—the article was offered as a gargle for sore throat and its label failed to bear a statement warning that severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting, may be serious and a physician should be consulted; and that the article should not be administered to children under 3 years of age unless directed by a physician.

DISPOSITION: 5–1–62. Default—destruction.

7085. Abunda Beauty device. (F.D.C. No. 47208. S. Nos. 21–912/13 T.)

QUANTITY: 22 individually ctnd. devices at Albuquerque, N. Mex.

SHIPPED: 9–7–60, from Menlo Park, Calif., by Pam Pro Plastics, to Albuquerque, N. Mex., where it was picked up by James E. Henderson, t/a Abunda Beauty of New Mexico and delivered to the dealer through Joseph Ruffino, representative of Abunda Beauty Products, San Mateo, Calif.

LABEL IN PART: (Ctn.) "Abunda Beauty by Abunda Products, 20 Forty First Avenue, San Mateo, California."

ACCOMPANYING LABELING: Leaflets entitled "Abunda Beauty . . . A New World of Loveliness" and booklets entitled "Abunda Beauty . . . A Lovelier You," "Abunda Hydro Massage Bosom Beauty," and "General Information * * * Get Acquainted With."

RESULTS OF INVESTIGATION: Examination of a similar device collected previously showed the article to be a plastic cup-shaped device with a water hose attachment. In use, the cup was intended to be placed over the female breast with the hose attachment connected to the household water service. The water was caused to be diffused or "swirled" in passing through a perforated disc in the cup base. The swirling water within the cup reportedly served to massage the bust.

LIBELED: 3–14–62, Dist. N. Mex.

CHARGE: 502(a)—when shipped and while held for sale, the name "*Abunda Beauty*" and the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; and for providing an abundant bust through hydrotherapy: and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for use on the female breast.

DISPOSITION: 4–17–62. Default—destruction.

7086. Oscilloclast, Pedasine, and Pathoclast devices. (F.D.C. No. 47570. S. No. 57–274 T.)

QUANTITY: 1 *Oscilloclast device*, 1 *Pedasine device*, and 1 *Pathoclast device*, at Oklahoma City, Okla., in possession of Tauschers Natural Food Store.

SHIPPED: (*Oscilloclast device*) sometime in 1953, from San Francisco, Calif., by Electronic Medical Foundation; (*Pedasine device*) sometime in 1938 or 1939, from Glendale, Calif.; and (*Pathoclast device*) sometime in 1948 or 1949, from Chicago, Ill., by Pathometric Laboratories, Inc.

LABEL IN PART: (Metal plate on device) "Short Wave Oscilloclast" and "The Pathoclast Pathometric Laboratories, Inc. Chicago."

ACCOMPANYING LABELING: Instruction booklets, reading in part, "Standard Floor Model Short Wave Oscilloclast" and "Shortwave Oscilloclast Oscillitron 1953 Electronic Medical Foundation * * * San Francisco 9, California" and instruction manuals, reading in part, "Cross-Index to Pathometric Rates by Elizabeth W. Page * * * October 1949" and "Table of Contents Connecting Instrument 2 Treatment 11 Pathoclast Analysis 1 * * * Subject Index 87."

RESULTS OF INVESTIGATION: The *Oscilloclast device* was a floor-type cabinet with a sloping control panel on the tip, which panel contained a timer, ten push buttons, two lights, a power switch, and connections for four electrodes; that the *Pedasine device* was a suitcase-type device which consisted of a synchronous motor-controlled sinusoidal current generator and contained four metal plate electrodes, switches, an intensity control, and external pad electrodes; and that the *Pathoclast device* was a desk console-type electrically operated diagnostic and therapeutic device with a control panel and circuiting on top of the desk containing a variety of meters, knobs, dials, switches, lights, and specimen wells for the operation of the device, and that the electronic components of such device were intended to measure the electrical vibrations from the body and reradiate similar radiations through the electrodes to the body.

LIBELED: 5–17–62, W. Dist. Okla.

CHARGE: 502(a)—when shipped and while held for sale, (*Oscilloclast*) the labeling accompanying the device contained false and misleading representations that the article was adequate and effective as a treatment for overcoming acidosis, bubonic plague, diabetes, malaria, polio, radium burn, tuberculosis, warts, and (*Pathoclast*) the labeling accompanying the device contained false and misleading representations that the article was adequate and effective as a treatment for overcoming diseases of the kidneys, lungs, nerves, heart, liver, pituitary, spleen, and other organs; and 502(f)(1)—(*Oscilloclast* and *Pathoclast*) when shipped and while held for sale, and (*Pedasine*) while held for sale, the labeling failed to bear adequate directions for use and the articles were not exempt from that requirement since the devices were not safe for use except under the supervision of a practitioner licensed by law to direct the use of such devices, and the labeling failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a physician" and the devices were not in the possession of a person who was regularly and lawfully engaged in the distribution of prescription devices and were not in the possession of a practitioner licensed in the State of Oklahoma to use, or order the use of, such devices.

DISPOSITION: 6–20–62. Default—delivered to the Food and Drug Administration.

7087. Electro Sine Galvanic device. (F.D.C. No. 45815. S. No. 67–356 R.)

QUANTITY: 1 device at Dallas, Tex.

SHIPPED: 10–12–59, from Tiffin, Ohio, by L. L. Roby Manufacturing Corp.

LABEL IN PART: (Front) "Electro Sine Galvanic Model 200" and (back) "Manufactured by L. L. Roby Manufacturing Corp., Tiffin, Ohio."

RESULTS OF INVESTIGATION: The device was a small suit-case-type container housing an electronic circuit for the production of various forms of electrical current. The control panel contained a switch, pilot lights, a 0–25 DC ma meter, and an array of knobs for the selection and adjustment of the current type, intensity, and frequency. This panel also had three female outlet plugs to which the applicators were attached and one plug labeled "foot switch." The device produced surged, pulsating, or continuous faradic pulses and a galvanic current. Included were two sets of electrodes, cloth pads 1¾ inches in diameter, and two metal strips.

LIBELED: 6–19–61, N. Dist. Tex.; amended libel 9–8–61.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling failed to bear adequate directions for use.

DISPOSITION: 4–23–62. Consent—decree provides that device may be taken down under bond by claimant, L. L. Roby Manufacturing Corp., to be brought into compliance with the law.

7088. Lindquist Chronosonic Ultrasound device. (F.D.C. No. 47387. S. Nos. 83–361/2 P.)

QUANTITY: 2 devices at Welch, Okla.

SHIPPED: 4–9–56 and 6–27–57, from Los Angeles, Calif., by R. J. Lindquist Co.

LABEL IN PART: (Front of device) "Lindquist Chronosonic Ultrasound R. J. Lindquist Co. 2419 W. 9th Street Los Angeles 6, Calif. * * * Model 401 * * * Serial 7150 [or "7384"]."

ACCOMPANYING LABELING: "Bare Drugless Arthritis Cure" reprint from Los Angeles Herald Examiner, Friday, July 16, 1954; "Prolapse of Intervertebral Discs" reprint from The British Journal, May 1952; "The Myofascial Genesis of Pain" reprint from May 1952 Postgraduate Medicine, Vol. 11, No. 5; "What a Therapist May Expect From Ultrasound" by Frank Stephen Zach, M.D.; "Therapeutic Application of Ultrasound Energy" reprint from the Journal of the Florida Medical Assoc. 43: 341–346 (Oct.) 1956; "Ultrasonic Therapy: A Review of its Present Status and Future Possibilities" by Kenneth Phillips, M.D. C.A.C.P., Miami, Florida; "Ultrasonics in Biology and Medicine" English language edition of Ultraschall in Medizin und Grenzgebieten, Vol. 1, No. 1, 1956; "Silent Sound" leaflet reprint from "Parade," May 13, 1956; "The Application of Ultrasound in Physical Medicine" by E. F. Carter, Sr., Director, Dept. of Physical Med., Tampa Municipal Hospital; "Use of Sound to Treat Disease to be Demonstrated to Medics" reprint from The Miami Herald, Sunday, Nov. 9, 1952, by Bert Collier; "Treatment With Ultra-sound Waves" by E. F. Carter, M.D., Head of Dept. of Physical Med., Tampa Municipal Hospital, Tampa, Florida; "Use of Ultrasonation in an Orthopedic Practice" by Harry Alban, M.D. F.A.S.C., Long Beach, California; "Ultrasonics and Therapy" reprint from page 46 of Radio-Electronics for November 1951; "Ultrasonic Therapy" reprint from The Physical Therapy Review, Vol. 34. No. 11, November 1954; "Ulcers Are Cured—Sound Waves Used for The Relief of Pain" reprint from page 8–A, Miami Daily News, Sunday, November 9, 1952; "A Few Cases Treated With Ultrasound" leaflet by Dr. E. F. Carter, M.D.; "Lindquist Chronosonic Ultrasound Generator Portable Model No. 401 with Model 90 Soundhead" descriptive leaflet by R. J. Lindquist Co.; "Technical Application of Ultrasound in Therapy (& insert) Spinal Levels of Referred Inner Organs" instructions for use of Chronosonic Ultrasound Model 401 in treating areas of the human body; "Ultrasound Therapy" by Miller & Weaver, reprinted from The Physical Therapy Review, Vol. 34, No. 11, November 1954.

RESULTS OF INVESTIGATION: The article was an electronic high-frequency oscillator circuit of the self-rectifying type, having a pulsed power output and a soundhead applicator which generated the ultrasound energy. The circuit was enclosed in a simulated leather case with storage space for the electrical wires and soundhead. The gray "hammertone" panel contained a milliampere meter, internal timer with automatic shutoff, tuning control, and a 10-position power control. The soundhead was connected to the instrument circuit through a flexible coaxial cable.

LIBELED: 3–20–62, N. Dist. Okla.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, bursitis, arteriosclerosis, and other crippling and killing diseases; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 9–14–62. Default—the devices were ordered to be delivered to the Food and Drug Administration; the accompanying labeling was destroyed.

7089. Neurolinometer device. (F.D.C. No. 47715. S. No 70–894 T.)

QUANTITY: One device at Hamlin, Tex.

SHIPPED: During November 1955, from Cumberland, Wis., by William A. Patillo, D. C.

RESULTS OF INVESTIGATION: Examination indicated that the device was housed in a black, suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten" "one" "cervical" or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

LIBELED: 8–8–62, N. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, the label statement "This instrument has no known analytical or therapeutic value," was misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; 502(b)(1)—the label failed to bear the name of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, the diagnosis of disease in man, in that the article was worthless for use for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 9–26–62. Default—destruction.

DRUG FOR VETERINARY USE*

7090. **Dr. Mayfield's Turkey Prescription.** (F.D.C. No. 46155. S. No. 54–596 R.)

QUANTITY: 1 keg containing 16 unlabeled 5-lb. bags at Lone Rock, Wis.

SHIPPED: 4–24–61, from Charles City, Iowa, by Dr. Mayfield Laboratories.

LABEL IN PART: (Keg) "Dr. Mayfield Turkey Prescription Net Weight 20–5 pounds * * * Active ingredients: Sodium Arsanilate, each ounce contains 94 grains arsenic expressed as arsenic trioxide * * * manufactured by Dr. Mayfield Laboratories, Charles City, Iowa."

RESULTS OF INVESTIGATION: Analysis showed the product to be a pinkish-white, finely ground powder containing essentially the amount of arsenic trioxide declared on its label.

LIBELED: 8–2–61, W. Dist. Wis.

CHARGE: 502(b)—when shipped and while held for sale, the article failed to bear a label (bag) containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of quantity of contents; 502(e)(2)—its label failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 4–25–62. Consent—claimed by Lone Rock Milling Co., Lone Rock, Wis., and released under bond to be relabeled.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

7091. **Various medicines and antibiotic drugs.** (F.D.C. No. 44993. S. No. 35–990 R.)

QUANTITY: 7 ctns., containing a total of 542 lbs., at Brooklyn, N.Y.

SHIPPED: The articles were delivered, on 9–6–60, to a ship pier at Brooklyn, N.Y., for shipment to Reykjavik, Iceland.

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*See also No. 7068.

RESULTS OF INVESTIGATION: Examination showed that the articles were submerged in polluted river water. The contamination occurred as a result of a storm on 9–13–60, which flooded the pier where the articles were stored.

LIBELED: 10–13–60, E. Dist. N.Y.

CHARGE: 501(a)(2)—while in interstate commerce, the articles were held under insanitary conditions.

DISPOSITION: 3–17–61. Consent—claimed by Stefan Thorarensen, Ltd., and released for reconditioning. The articles proved to be unfit for use and were destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE

7092. Imitation Diuril tablets. (F.D.C. No. 45557. S. Nos. 7–596 R, 53–481 R.)

INFORMATION FILED: 3–14–61, Dist. Mass., against Saul Bogdanov, t/a Victory Pharmacal Co., Roxbury, Mass.

ALLEGED VIOLATION: Prior to 7–11–60, the defendant caused a quantity of chlorathiazide tablets to be offered for sale and sold as Diuril tablets which act resulted in the tablets being misbranded.

CHARGE: 501(d)(2)—*imitation Diuril tablets* had been substituted for Diuril tablets; 502(i)(2)—the article was an imitation of another drug, Diuril; and 502(i)(3)—the article was offered for sale under the name of another drug, Diuril.

PLEA: Not guilty.

DISPOSITION: On 6–5–61, the case came to trial before the court and jury. On 6–7–61, the jury returned a verdict of not guilty.

7093. Tri-Tabs. (F.D.C. No. 46600. S. Nos. 17–989/90 R, 17–993 R.)

QUANTITY: 14 5,000-tablet ctns., 23 1,000-tablet btls., 2 500-tablet btls., and 34,000 tablets in unlabeled strip-paks of *Tri-Tabs Purple;* 5 5,000-tablet ctns., 6 1,000-tablet btls., and 9,000 tablets in unlabeled strip-paks of *Tri-Tabs Yellow;* and 10 5,000-tablet ctns., 24 1,000-tablet btls., 2 500-tablet btls., and 32,000 tablets in unlabeled strip-paks of *Tri-Tabs Pink*, at Denver, Colo., in possession of Western Research Laboratories.

SHIPPED: On 8–28–58 and 2–17–61, from St. Louis, Mo., by Keith Victor Pharmacal Co.

LABEL IN PART: (Btl. and ctn.) "Tablets TRI-TABS PURPLE (TPT) * * * Each Tab Contains: (Dextro Amphetamine Hydrochloride) 15 mg. * * * Manufactured by Western Research Laboratories Denver, Colorado" and "Tablets TRI-TABS YELLOW (TTY) [or "TRI-TABS PINK (TTP)"] One-A-Day Divided Dose Tablets Each Tablet Contains: (Dextro Amphetamine Hydrochloride) 15 mg. * * * AVERAGE DOSE: Adults, 1 tablet on arising (provides relatively the same therapeutic effect for one-third the total dose taken t.i.d.) * * * Manufactured by Western Research Laboratories Denver, Colorado."

RESULTS OF INVESTIGATION: The articles were shipped in bulk and repacked by the dealer as described above. Analysis of the articles showed that *Tri-Tabs Purple* contained from 65 to 124 percent of the declared amount of dextroamphetamine hydrochloride which was released in a uniform manner over a period of 7 hours; *Tri-Tabs Yellow* contained from 76 to 131 percent of the

declared amount of dextro-amphetamine hydrochloride which was released completely within 1 hour; and *Tri-Tabs Pink* contained from 74 to 137 percent of the declared amount of dextro-amphetamine hydrochloride which was released in a uniform manner over a period of 7 hours or of which about 50 percent was released in 2 hours.

LIBELED: 10–30–61, Dist. Colo.; amended libel 3–19–62.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the articles differed from that which they purported and were represented to possess, namely, 15 milligrams of dextro-amphetamine hydrochloride in each tablet, since the dextro-amphetamine hydrochloride content of the tablets ranged from 9.70 to 13.34 milligrams per tablet, and from 17.35 to 20.62 milligrams per tablet; and 502(a)—when shipped and while held for sale, the label statement "Each Tablet Contains: (Dextro Amphetamine Hydrochloride) 15 mg." was false and misleading since each tablet does not contain 15 mgs. of dextro-amphetamine hydrochloride; and (*Tri-Tabs Yellow* and *Tri-Tabs Pink*) when shipped and while held for sale, the label statement "One-A-Day Dividend Dose Tablets * * * provides relatively the same therapeutic effect of one-third the total dose taken t.i.d. (three times daily)" was false and misleading since the articles did not provide the same therapeutic effect as one-third the total dose taken three times daily.

DISPOSITION: 4–19–62; amended decree 4–30–62. Default—destruction.

7094. Span-RD time disintegrating capsules. (F.D.C. No. 46792. S. Nos. 18–007/8 T.)

QUANTITY: 1 40,300-capsule drum, 10 1,000-capsule btls., 33 500-capsule btls., and 58 cases, 11 100-capsule btls. each of *Span-RD;* and 1 82,900-capsule drum, 12 500-capsule btls., and 20 cases, 12 50-capsule btls. each, of *Span-RD 12*, at Houston, Tex.

SHIPPED: Between 5–16–61 and 6–14–61, from Hoboken, N.J., by Kingston Laboratories, Ltd.

LABEL IN PART: (Btl.) "Span-RD (Ratiodrine Sustained Release Capsules) Each Time Disintegrating Capsule Contains: d-Methamphetamine HCl 12 mg. dl-Methamphetamine HCl 6 mg. Butabarbital 30 mg. Warning: * * * Caution * * * Average Dose: * * * Metro Med. Inc. Houston, Texas" and "Span-RD 12 (Ratiodrine Sustained Release Capsule) Each Time Disintegrating Capsule Contains: d-Methamphetamine HCl 8 mgs. dl-Methamphetamine HCl 4 mgs. Butabarbital 30 mgs. Warning * * * Caution * * * Usual Dose * * * Metro Med. Inc. Houston, Texas."

RESULTS OF INVESTIGATION: Analysis showed that the articles contained (*Span-RD*) approximately 78 percent of the declared amount of butabarbital sodium and approximately 87 percent of the declared amount of methamphetamine hydrochloride; and (*Span-RD 12*) approximately 74 percent of the declared amount of butabarbital sodium and approximately 79 percent of the declared amount of methamphetamine hydrochloride; and that the capsules (both lots) would disintegrate completely in simulated gastric fluid in approximately two hours.

The articles in the bottles were repacked from the bulk drums after shipment.

LIBELED: 12–22–61, S. Dist. Tex.

CHARGE: 501(c)—when shipped, the strength of the articles differed from, and their quality fell below, that which they purported to possess, since the

articles contained less than the labeled amounts of butabarbital sodium and methamphetamine hydrochloride, respectively, and since the capsules failed to disintegrate in a uniform manner as stated on the labels, over a period of one day.

DISPOSITION: 5–17–62. Default—destruction.

7095. **Pentobarbital sodium capsules.** (F.D.C. No. 47277. S. No. 32–298 T.)

QUANTITY: 118 500-capsule btls. at Wilmington, Calif.

SHIPPED: 11–30–61, from Newark, N.J., by Benson Pharmacal Corp.

LABEL IN PART: (Btl.) "500 Capsules * * * Sodium Pentobarbital Capsules U.S.P. 1½ Grain (100 Mg.) * * * Manufactured by Pharmacaps, Inc., Elizabeth, N.J. Distributed by Benson Pharmacal Corp., Newark, N.J."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to meet the requirements of the United States Pharmacopeia for capsule weight variation.

LIBELED: 4–3–62. S. Dist. Calif.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as *pentobarbital sodium capsules*, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality fell below the standards set forth in such compendium for capsule weight variation.

DISPOSITION: 4–30–62. Default—destruction.

7096. **Chorionic gonadotropin.** (F.D.C. No. 47051. S. No. 26–550 T.)

QUANTITY: 1 ctn., containing 74 unlabeled vials and 3 ctns., containing 100 unlabeled vials each, at Detroit, Mich.

SHIPPED: 6–22–60, from New York, N.Y.

LABEL IN PART: (Ctn.) "100 x 10 cc. Multiple Doses: Chorionic Gonadotropin 2500 I.U. For Intramuscular use only * * * Caution."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared potency of *chorionic gonadotropin*.

LIBELED: 2–19–62, E. Dist. Mich.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess.

DISPOSITION: 4–19–62. Default—destruction.

7097. **Sher-Opth injection and Sher-Otic injection.** (F.D.C. No. 47376. S. Nos. 16–674/5 T.)

QUANTITY: 21 boxes, 12 5-cc. vials each, of *Sher-Opth* and 72 boxes, 12 10-cc. vials each, of *Sher-Otic*, at Louisville, Ky.

SHIPPED: 7–12–60 and 12–13–61, from St. Louis, Mo., by E. W. Heun Co.

LABEL IN PART: (Vial) "Sher-Opth Sterile Antibiotic Steroid Ophthalmic Suspension Each cc. contains: * * * Hydrocortisone U.S.P. 5 mg. * * * Mfg. for Sheryl Pharmaceuticals, Inc. Louisville, Ky." and "Sher-Otic Steroid, Antibiotic, Anesthetic, Antihistamine, Anti-Inflammatory Each cc. contains: * * * Hydrocortisone, U.S.P. 5 mg. * * * Mfg. for Sheryl Pharmaceuticals, Inc. Louisville, Ky."

RESULTS OF INVESTIGATION: Analyses showed that the articles contained (*Sher-Opth*) 58 percent and (*Sher-Otic*) 80 percent of the declared amounts of hydrocortisone U.S.P.

LIBELED: 3–16–62, W. Dist. Ky.

CHARGE: *Sher-Opth*, 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; *Sher-Otic*, 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Hydrocortisone U.S.P. 5 mg." was false and misleading as applied to a product containing less than the declared amount of hydrocortisone.

DISPOSITION: 6–21–62. Default—destruction.

7098. Sulfathiazole tablets. (F.D.C. No. 46797. S. No. 3–676 T.)

QUANTITY: 37,800 tablets in a drum at Huntington, W. Va.

SHIPPED: 3–7–61, from Dayton, Ohio, by Superior Pharmacal Co.

LABEL IN PART: (Drum) "Tablets Compressed Private Formula No. 4405 Sulfathiazole Each represents: Sulfathiazole 7.7 grs. Warning * * * Caution * * * 20933 The Superior Pharmacal Co. Dayton, Ohio."

LIBELED: 12–20–61, S. Dist. W. Va.

CHARGE: 501(b)—when shipped, the quality of the article fell below the standard for *sulfathiazole tablets* set forth in the National Formulary since such standard requires that *sulfathiazole tablets* disintegrate in 1 hour, whereas tablets of the article failed to do so.

DISPOSITION: 5–11–62. Consent—claimed by Superior Pharmacal Co. and brought into compliance with the law.

7099. Li-Co-Fol liver injection. (F.D.C. No. 47132. S. No. 6–795 T.)

QUANTITY: 33 individually ctnd. vials at Lawrence, Mass.

SHIPPED: 8–29–61, from New York, N.Y.

LABEL IN PART: (Vial and ctn.) "10 cc. Multiple Dose Vial Li-Co-Fol * * * Each cc. contains: * * * Vitamin B_{12} U.S.P. 100 mcg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 50 percent of the declared amount of vitamin B_{12}.

LIBELED: 2–12–62, Dist. Mass.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Vitamin B_{12} U.S.P. 100 mcg." was false and misleading as applied to a product containing less than the declared amount of vitamin B_{12}.

DISPOSITION: 3–26–62. Default—destruction.

7100. **Vitamin B_{12} concentrate.** (F.D.C. No. 47233. S. No. 54–096 T.)

QUANTITY: 396 100-tablet btls. at Michigan City, Ind.

SHIPPED: 12–29–60 and 5–8–61, from El Segundo, Calif., by Rabin Winters Corp.

LABEL IN PART: (Btl.) "Rabin Pharmaceuticals 100 Tablets Vitamin B_{12} Concentrate 25 Micrograms * * * Each Tablet contains Activity Equivalent to 25 Mcg. of Cyanocobalamin."

RESULTS OF INVESTIGATION: Examination showed that the article contained about 80 percent of the declared amount of vitamin B_{12}.

LIBELED: 3–9–62, N. Dist. Ind.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Vitamin B_{12} Concentrate 25 Micrograms" was false and misleading as applied to a product containing less than the declared amount of vitamin B_{12}; and when

shipped, the name "Vitamin B_{12} Concentrate" and statements in its labeling declaring composition of the article, were misleading since they failed to reveal the material fact as to whether the active ingredient was cyanocobalamin or cobalamin concentrate.

DISPOSITION: 5–18–62. Default—destruction.

7101. Vitamin capsules. (F.D.C. No. 46888. S. No. 28–201 T.)

QUANTITY: 2 drums containing 20,000 capsules at Mission, Kans.

SHIPPED: Sometime in 1957, from Long Island City, N.Y.

LABEL IN PART: (Drum) "Special Formula * * * Tablets: 12,750 Each * * * Capsule Contains: * * * Ascorbic Acid 50 Mgm."

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 60 percent of the declared amount of vitamin C.

LIBELED: 1–5–62, Dist. Kans.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Ascorbic Acid 50 Mgm." was false and misleading as applied to a product containing less than the declared amount of ascorbic acid.

The libel alleged also that another article was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 5–23–62. Default—destruction.

7102. Digitalis tablets. (F.D.C. No. 47256. S. No. 47–559 T.)

QUANTITY: 22 1,000-tablet btls. at St. Louis, Mo., in possession of TMCO Pharmaceuticals, Inc.

SHIPPED: During August 1960, from New York, N.Y.

LABEL IN PART: (Btl.) "TMCO Digitalis EC 1,000 Tablets Each Tablet Contains Digitalis USP 100 Mg. * * * Manufactured for TMCO Pharmaceuticals, Inc."

RESULTS OF INVESTIGATION: Analysis showed that the article contained significantly less than the declared amount of digitalis. The article was shipped, as described above, in the form of bulk digitalis powder and, after shipment, was made into tablets by another local firm.

LIBELED: 3–23–62, E. Dist. Mo.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, *digitalis tablets*, the name of which is recognized in the U.S. Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Digitalis USP 100 Mg." was false and misleading as applied to a product containing significantly less than the declared amount of digitalis.

DISPOSITION: 5–21–62. Default—destruction.

7103. Analritic tablets, Salisone tablets, and Daligesic tablets. (F.D.C. No. 47615. S. Nos. 38–161/3 T.)

QUANTITY: 27 cases, 12 100-tablet btls. each, of *Analritic;* 29 cases, 12 100-tablet btls. each, of *Salisone;* and 26 cases, 12 100-tablet btls. each, of *Daligesic*, at Rainsville, Ala.

SHIPPED: 11–11–59, from Greer, S.C.

LABEL IN PART: (Btl.) "Analritic ["Salisone" or "Daligesic"] Upstate * * * Mfg'd For Upstate Laboratories Rainsville, Alabama."

RESULTS OF INVESTIGATION: Analysis showed that the articles were undergoing decomposition, as evidenced by the presence therein of free salicylic acid crystals and a strong odor of acetic acid.

LIBELED: 5-22-62, N. Dist. Ala.

CHARGE: 501(c)—while held for sale, the purity, quality, and strength of the articles differed from that which they were purported to possess in that they were undergoing decomposition.

DISPOSITION: 6-22-62. Default—destruction.

DRUGS FOR VETERINARY USE*

7104. **Commercial egg ration.** (F.D.C. No. 46367. S. No. 24-089 R.)

INFORMATION FILED: 1-30-62, Dist. Nebr., against G. E. Conkey Co., a corporation, Nebraska City, Nebr., and Harold E. Fouts.

SHIPPED: Between 2-25-60 and 3-29-60, from Nebraska to Missouri.

LABEL IN PART: (Bag) "Hi-C-50 Complete Commercial Egg Ration Active Drug Ingredients Furazolidone 0.011% Oxytetracycline .025 grams per pound Manufactured by G. E. Conkey Co. Nebraska City, Nebraska."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amounts of furazolidone and oxytetracycline.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess.

PLEA: Nolo contendere.

DISPOSITION: 6-21-62. Corporation—$100 fine, plus costs; Fouts—$100 fine.

7105. Medicated feed. (F.D.C. No. 47467. S. No. 20-462 T.)

QUANTITY: 37 50-lb. bags at Stillwater, Okla.

SHIPPED: 3-1-61, from Peoria, Ill., by Dawe's Laboratories, Inc.

LABEL IN PART: (Tag) "Stillwater Swine Premix File No. 4031-D Medicated For Growth Stimulation Active Drug Ingredient: Arsanilic Acid, 2.0% Manufactured for: Stillwater Milling Co. Stillwater, Okla."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 67.9 percent of the declared amount of arsanilic acid.

LIBELED: 4-25-62, W. Dist. Okla.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Arsanilic Acid, 2.0%" was false and misleading.

DISPOSITION: 6-13-62. Default—delivered to a charitable institution.

7106. Min-A-Sul. (F.D.C. No. 47613. S. No. 58-645 T.)

QUANTITY: 68 40-oz. jars and 11 10-lb. jars at Greene, Iowa.

SHIPPED: 3-21-62 and 4-9-62, from Kenyon, Minn., by Valley Vet Supply.

LABEL IN PART: (Jar) "Min-A-Sul Combination Sulphas with Mineral * * * Active Ingredients—100% Sulphamethiazine, Sulphanilamide, Sulphathiazole * * * Distributed by Valley Vet Supply, Willmar, Minnesota."

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*See also No. 7065

ACCOMPANYING LABELING: Leaflets entitled "Min-A-Sul For Mastitis and Infected Udders."

LIBELED: On or about 5–23–62, N. Dist. Iowa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess since the sulfonamide content was less than that declared on the label; 502(a)—the label statement "Active Ingredients–100% Sulphamethiazine, Sulphanilamide, Sulphathiazole" was false and misleading as applied to a product which contained insignificant amounts of sulfonamides; and 502(a)—the labeling contained false and misleading representations that the article, when used as directed, was adequate and effective as a treatment for overcoming mastitis and infected udders in cows, swollen and infected udders in sows and sheep, and for overcoming intestinal diseases in swine.

DISPOSITION: 6–22–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

7107. Rectal suppositories. (F.D.C. No. 45551. S. Nos. 43–577/8 R.)

INFORMATION FILED: 11–9–61, Dist. N.J., against Knoll Pharmaceutical Co., a corporation, Orange, N.J.

SHIPPED: Between 2–11–60 and 4–11–60, from New Jersey to California.

LABEL IN PART: (Box) "6 Rectal Suppositories 3 mg. (1/20 gr) each Dilaudid Hydrochloride (brand of dihydromorphinone HCl) Warning: May be habit forming. POISON Usual Dose: Adult - 1 suppository; children – one-half suppository. Caution: Federal law prohibits dispensing without prescription. Knoll Pharmaceutical Company, Orange, New Jersey NEW SHAPE AND STRENGTH Vegetable Fat Base."

CHARGE: 502(a)—when shipped, the label statement "Rectal Suppositories 3 mg. (1/20 gr) each Dilaudid Hydrochloride * * * Usual Dose: Adult – 1 suppository; children – one-half suppository" was false and misleading, since each suppository would not release 3 mg. of Dilaudid hydrochloride in that each suppository would not melt at body temperature.

PLEA: Nolo contendere.

DISPOSITION: 5–4–62. $500 fine.

7108. Instant Protein. (F.D.C. No. 45754. S. No. 12–862 R.)

QUANTITY: 11,586 8-oz. cans at Chicago, Ill., in possession of Rexall Drug Co.

SHIPPED: 2–14–61, from St. Louis, Mo., by Rexall Drug Laboratory.

LABEL IN PART: (Can) "Rexall Chocolate Instant Protein * The Natural Protein Concentrate * * * Rexall Drug Company Pharmaceutical Chemists * * * St. Louis."

ACCOMPANYING LABELING: Leaflet entitled "Now Live All Of The Day All Of The Way if protein lack is slowing you down."

LIBELED: 4–28–61, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of tiredness and

*See also Nos. 7063, 7064, 7071, 7072, 7076–7079, 7081–7086, 7088, 7089, 7093, 7099–7102, 7105.

conditions causing the body to slow down; for the control of weight; to promote good health, vitality, youthful vigor, beauty, beautiful color and texture of the skin, elasticity, resilience and luster of the hair, and strong, nourished, and toned muscles to hold the body erect; build strong muscles; promote circulation in older people; and cause older people to look and feel better.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgement on foods.

DISPOSITION: 4–30–62. Consent—claimed by Rexall Drug & Chemical Co. and released under bond for relabeling.

7109. Elixir Bewon (thiamine chloride). (F.D.C. No. 47030. S. Nos. 35–857/8 T.)

QUANTITY: 59 1-gal. btls. and 162 1-pt. btls. at Minneapolis, Minn.

SHIPPED: 12–15–61 and 1–18–62, from Philadelphia, Pa., by Wyeth Laboratories, Inc.

LABEL IN PART: (Btl.) "One Pint 1A13 [or "One Gallon 1Z13"] Elixir Bewon Elixir Thiamine Chloride * * * Promotes the Appetite Each Fluidounce Contains 500 International Units of Crystalline Vitamin B_1 (Thiamine Chloride) * * * Dose: * * * Wyeth Laboratories, Inc. Philadelphia, Pa."

LIBELED: 2–14–62, Dist. Minn.

CHARGE: 502(a)—when shipped, the label statement "Promotes the Appetite" was false and misleading since the article was not adequate and effective for such purpose.

DISPOSITION: 4–6–62. Default—destruction.

7110. Luscoe Peter's Remedy. (F.D.C. No. 47423. S. No. 14–494 T.)

QUANTITY: 114 individually ctnd. btls. at Chicago, Ill.

SHIPPED: 1–24–62, from Buffalo, N.Y., by Luscoe Products, Inc.

LABEL IN PART: (Btl. and ctn.) "Luscoe Peter's Remedy Active Ingredients: Fldext, Buckthorn, Senna, Culver's Root, Special Cascara Aromatic, and other non-active ingredients. * * * Made by Luscoe Products, Inc. Buffalo * * * For Temporary Relief of Gastro-Intestinal Disturbances * * * Sold in Canada as Gastrodex new improved formula."

LIBELED: 3–29–62, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for temporary relief of gastrointestinal disturbances, and the names, "*Luscoe Peter's Remedy*" and "Gastrodex" and the directions in the labeling, when viewed in the setting in which they appeared, made false and misleading representations that the article was adequate and effective for use in gastrointestinal disorders.

DISPOSITION: 4–25–62. Default—destruction.

7111. Zinsep Compound. (F.D.C. No. 46738. S. No. 28–220 T.)

QUANTITY: 112 individually ctnd. 11-oz. btls. at Kansas City, Mo.

SHIPPED: 8–26–61 and 10–3–61, from Kansas City, Kans., by Union Pharmacal Co.

LABEL IN PART: (Ctn.) "Improved Zinsep Compound Antacid (11 Fluid Ounces) * * * Manufactured by Union Pharmacal P.O. Box 8105 Kansas City, Missouri * * * Active Ingredients: Magnesia Carbonate, U.S.P., Magnesia Trisili-

cate, U.S.P., Bismuth Subcarbonate, U.S.P., Sodium Salicylate, U.S.P., Peppermint Oil, U.S.P., Fluid Extract Cascara" and (btl.) "12 Fluid Ounces Zinsep Compound Antacid Gas Eliminant * * * Caution: * * * Manufactured by Union Pharmacal Co. P.O. Box 8105 Kansas City 12, Mo."

ACCOMPANYING LABELING: Leaflet in carton entitled "Zinsep Finest Healing Ulcer Medication You Ever Used America's Greatest Stomach Remedy."

LIBELED: On or about 11–28–61, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective in the treatment for overcoming stomach and intestinal pains; permanently correcting stomach disorders; correcting digestive disorders; relieving chronic stomach disorders; correcting conditions causing acid dyspepsia, nausea, vomiting, sour stomach, belching, flatulence, bloating, heartburn, sick headache, and bad breath; and healing stomach ulcers.

DISPOSITION: 4–24–62. Default—destruction.

7112. **Pine oil.** (F.D.C. No. 45700. S. No. 58–295 R.)

QUANTITY: 1 50-lb. drum and 600 btls. at Spartanburg, S.C., in possession of Walter O. Ezell, t/a Pine-A-Cura Co. and Geer Drug Co.

SHIPPED: 4–1–60, from Wilmington, Del.

LABEL IN PART: (Btl.) "Pure Pine Oil Pine-A-Cura * * * Long Leaf Pine Healing Oil * * * Distributed by Pine-A-Cura Co., Spartanburg, S.C."

RESULTS OF INVESTIGATION: The article in the bottles was repacked by the dealer from bulk stock shipped as described above.

LIBELED: 4–17–61, W. Dist. S.C.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for healing old sores, cuts, bruises, ulcers, inflammation, rheumatism, sprains, burns, eczema, itch, poison oak, insect bites, toothache, croup, sore throat, and sunburn.

DISPOSITION: 5–7–62. Default—destruction.

7113. **Safflower oil capsules.** (F.D.C. No. 47403. S. No. 68–781 T.)

QUANTITY: 94 100-capsule btls. at Milwaukee, Wis., in possession of Sentials (Roselle Meyer, owner).

SHIPPED: 12–8–60, from Lynbrook, N.Y., by Barth Food Co., Inc.

LABEL IN PART: (Btl.) "Safflower Capsules * * * containing up to 74% Linoleic Acid from Safflower Seed Oil, plus Vitamin B-12, Inositol, Vitamin E, and Soya Bean Lecithin * * * Distributed by Roselle Meyer * * * Milwaukee."

ACCOMPANYING LABELING: Leaflets entitled "not just 1 . . . but New 4-Way Action To Help Control Cholesterol."

RESULTS OF INVESTIGATION: The leaflets were prepared by Roselle Meyer.

LIBELED: 3–19–62, E. Dist. Wis.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence therein of safflower oil, and that the article was adequate and effective to reduce and to control the cholesterol level of the blood, and to promote the utilization of fats.

DISPOSITION: 4–13–62. Default—destruction.

7114. **Safflower oil capsules.** (F.D.C. No. 47411. S. No. 5–151 T.)

QUANTITY: 90 42-capsule btls. and 30 84-capsule btls., with some of the articles being packed in display-type cartons, containing 6 42-capsule btls. and 4 84-capsule btls. each, at Baltimore, Md.

SHIPPED: 2–2–62, from Newark, N.J., by Welton Laboratories, Inc.

LABEL IN PART: (Btl.) "Welton safflower Oil With Vitamin B-6 * * * Packaged by Welton Laboratories, Inc., Newark 4, New Jersey" and (ctn.) "Safflower Oil With Vitamin B_6 Slim-Wel Diet Guide and Safflower Oil Story Welton Laboratories, Inc."

ACCOMPANYING LABELING: Booklets entitled "Diet Guide" and large and small window banners reading in part "Safflower Oil With Vitamin B-6."

LIBELED: 3–26–62, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence therein of safflower oil; and that the article was adequate and effective to reduce and control weight, even though consuming thousands of calories daily without regard to the total caloric intake; and to lower cholesterol levels of the blood.

DISPOSITION: 4–19–62. Default—destruction.

7115. **Formtabs tablets.** (F.D.C. No. 43485. S. No. 78–582 P.)

QUANTITY: 7 30-tablet btls. and 13 90-tablet jars at Allegan, Mich.

SHIPPED: 6–18–59, from Cleveland, Ohio, by Marlo Products Co.

LABEL IN PART: "Formtabs each tablet contains: Phenylpropanolamine Hydrochloride 25 Mgm. As an Appetite Depressant in the Control of excess weight. Directions—Caution—Distributed By Marlo Products Co., Cleveland, Ohio."

ACCOMPANYING LABELING: Leaflet entitled, "Reduce without dieting."

LIBELED: 10–19–59, W. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was effective as an appetite depressant in the control of excess weight, without the use of cruel diets.

DISPOSITION: 12–3–59. Default—destruction.

7116. **Sterling cider vinegar.** (F.D.C. No. 45515. S. No. 68–687 R.)

QUANTITY: 161 cases of 4 1-gal. btls. each, 118 cases of 24 16-oz. btls. each, and 84 cases of 12 32-oz. btls. each, at Tulsa, Okla.

SHIPPED: Between 8–2–60 and 12–30–60, from New York, N.Y., and Sterling, Mass., by Sterling Cider Co., Inc.

LABEL IN PART: (Btl.) "Sterling Cider Vinegar * * * Made Exclusively From the Juice of Fresh Whole Apples * * * ["For Dietary use" on 32-oz. bottle only] Made Only By Sterling Cider Co., Inc. Sterling, Mass."

ACCOMPANYING LABELING: Leaflets entitled "Saving Lives With Vinegar."

RESULTS OF INVESTIGATION: The leaflets were used in promotion of the sale of the article, and were received from the manufacturer.

LIBELED: 3–16–61, N. Dist. Okla.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of cough, chronic bronchitis, serious lung infection, bronchiectasis, resistant infections due to

Pseudomonas aeruginosa, cavities in lungs, ear infection, underweight condition, and chronic eye troubles.

DISPOSITION: 6–28–61. Consent—claimed by Sterling Cider Co., Inc., and, pursuant to claimants's request, released by the court to Akin Distributors, Inc., Tulsa, Okla. The court conditioned the release upon the submission of an affidavit by Akin Distributors, Inc., that there was no literature on the premises of such firm which in any way referred to a therapeutic or dietary characteristic of the cider vinegar as distributed by Sterling Cider Co., Inc. The court also ordered that the above-mentioned leaflets which had been seized be destroyed, and it enjoined Sterling Cider Co., Inc., from further distributing, publishing, or circulating, in association with its cider products, the leaflets entitled "Saving Lives With Vinegar." The court ordered further that the claimant should not store or hold its cider products upon the premises where any written, printed, or graphic matter is located which would result in the misbranding of such products and that the claimant should not deliver such products to any person in whose possession written, printed, or graphic matter is located which would result in their misbranding.

7117. Audivox Electrostatic Precipitator device. (F.D.C. No. 46427. S. No. 61–065 R.)

QUANTITY: 6 devices at Kansas City, Mo., in possession of Audivox-Ganther Co.

SHIPPED: Between 3–1–61 and 4–12–61, from Boston, Mass., by Audivox, Inc.

LABEL IN PART: "Audivox Electrostatic Precipitator."

ACCOMPANYING LABELING: Folders entitled "Audivox Electrostatic Precipitator" and window display placards entitled "Hay Fever Sufferers," "Asthma," "Sinus and Catarrh Conditions," "Hearing Loss," and "Only a Genuine Electrostatic Precipitator."

RESULTS OF INVESTIGATION: Examination indicated that the article was a walnut cabinet 11" x 15" x 15¾" containing a two-speed fan, an ozone source, and an electrostatic-type precipitator. The front of the device had two control switches for fan control and ozone control.

The folders entitled "Audivox Electrostatic Precipitator" had been shipped by Audivox, Inc., and the window display placards had been prepared by the dealer.

LIBELED: 8–31–61, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that use of the article was an adequate and effective treatment for removing 99.2 percent of pollen and germs from the home to protect the health of the family; and for removing germs responsible for peritonitis, bronchopneumonia, meningitis, scarlet fever, smallpox, measles, pleurisy, mastoiditis, pulmonary tuberculosis, respiratory discomforts, asthma, hay fever, sinusitis, and hearing loss.

DISPOSITION: 12–6–61. Consent—claimed by Audivox, Inc., and brought into compliance with the law.

7118. Safe-T-Sun lamp. (F.D.C. No. 47201. S. No. 34–957 T.)

QUANTITY: Two cartons, containing unassembled parts for 27 devices, at Le Center, Minn.

SHIPPED: 1–23–62 and 1–26–62, from Bridgeport, Pa., by Safe-T-Sun Corp.

LABEL IN PART: (Ctn.) "Part 2 * * * Glass Sun Lamp Safe-T-Sun Corp. Williamsburg, Va." and (filter envelope) "Assembly of Health Tan Sun Lamp * * * Operating Instructions."

ACCOMPANYING LABELING: Folder entitled "Yes! This is the amazing new Safe-T-Sun Health-Tan Sun Lamp That Can't Burn * * * the only truly safe sun lamp with built-in health benefits Catalina Model."

RESULTS OF INVESTIGATION: The accompanying literature and inspector's examination indicated the article to be a commercially available Sylvania ultraviolet lamp fitted with a polyester film filter and adjustable reflector. The unit was then fitted to a floor stand.

LIBELED: 3–8–62, Dist. Minn.

CHARGE: 502(a)—when shipped, the name "Health Tan Sun Lamp" and the labeling contained false and misleading representations that the article was adequate and effective as a treatment for relieving tired back, stiff neck, arthritic-like pains, skin problems, and aching muscles; toning the skin; and overcoming adolescent skin problems; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning; and that the article could be used as a "sun lamp that can't burn."

DISPOSITION: 4–23–62. Default—destruction.

7119. Beautypower device. (F.D.C. No. 46887. S. No. 40–825 T.)

QUANTITY: 193 devices at New York, N.Y., in possession of Beauty Power, Inc.

SHIPPED: Between 10–14–61 and 10–18–61, from Muncy, Pa.

LABEL IN PART: (Device) "Beauty Power."

ACCOMPANYING LABELING: Leaflets entitled "How To Use Beautypower" and "Beauty Power Contact Lotion . . . Why?"; reprints of advertisement in "The New York Times, Thursday, 12–1–60"; booklets entitled "The New Science of Beauty: Facial Exerciser * * * Rosalie Sands reveals for Beauty Power her exclusive Facial Exercises" and "Vogue's New Beauty Book."

RESULTS OF INVESTIGATION: Examination showed the article to be a plastic box about 8 x 8 x 16 inches in size. The *Beautypower device* had a dial and regulating switch which was apparently used to increase the electrical output of the device. The Beautypower unit had two female receptacles for connecting the device to the hand unit. The hand unit consisted of a plastic box about the size of an electric razor. The end of the hand unit had two female receptacles for inserting two sponge pieces soaked in water or contact solution to establish an electrical contact between the device and the face. These sponge pieces were applied to the portion of the body to be treated.

The accompanying labeling was printed locally on order of the dealer.

LIBELED: 1–5–62, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective to revitalize and restore resiliency to facial muscles; eradicate facial lines, sagging facial contours and double chin; tone flabby muscles and make them stronger, more elastic, and younger; stimulate circulation in the facial area; relieve tension; remove crepiness of skin and "dowager's hump"; and improve skin texture.

DISPOSITION: 4–12–62. Default—delivered to the Food and Drug Administration.

7120. Diatherapuncteur device. (F.D.C. No. 46483. S. No. 26–721 T.)

QUANTITY: 1 device at Toledo, Ohio, in possession of Dr. Walter Pontasch.

SHIPPED: 6–29–61, from Stuttgart, Germany. The article was imported by Dr. Walter Pontasch through the Port of Detroit, Mich., and transported by him from Detroit to Toledo, Ohio.

LABEL IN PART: (Metal plate on front of device) "K & F Diatherapuncteur."

ACCOMPANYING LABELING: Wall charts and booklets printed in the German language.

RESULTS OF INVESTIGATION: The inspector's photographs and the literature indicated the device to be a suitcase-type container containing an electrical circuit, a meter, dials, switches, and a variety of electrodes.

LIBELED: 10–3–61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective in diagnosing the functions and collective disturbances of the organs of the body; diagnosing organ fatigue, incipient pathological anatomical changes of the organs, and the conditions or extent of diseases; in treating all painful and spastic conditions, functional disturbances, incipient organic damages, lowered organ functions, hypertension, dysmenorrhea, spastic diseases, and hypotensive symptoms complex.

DISPOSITION: 4–27–62. Consent—claimed by Dr. Walter Pontasch and shipped back to Germany.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 7061 TO 7120

PRODUCTS

[1] (7081, 7083) Seizure contested.
[2] (7092) Prosecution contested.
[3] (7076) Seizure contested. Contains opinion of the court.

[1](7081, 7083) Seizure contested.
[3](7076) Seizure contested. Contains opinion of the court.
[4](7077) Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1](7081, 7083) Seizure contested.
[2](7092) Prosecution contested.
[4](7077) Injunction issued.

[1](7081, 7083) Seizure contested.
[3](7076) Seizure contested. Contains opinion of the court.
[4](7077) Injunction issued.

U.S. GOVERNMENT PRINTING OFFICE: 1963

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7121–7160

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 6, 1963.*

CONTENTS

692-469—63

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7121. (F.D.C. No. 46710. S. Nos. 23–714/15 R, 23–718 R, 85–566 R, 85–574 R.)

INFORMATION FILED: 4–25–62, W. Dist. Mo., against **Carmelo Guastello, Kansas City, Mo.**

CHARGE: Between 5–31–61 and 7–11–61, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–22–62. $750 fine.

7122. (F.D.C. No. 47108. S. Nos. 51–101/2 R.)

INFORMATION FILED: 6–21–62, Dist. N. Mex., against **Julius C. McNeil and James Melvin Grimes (employees of a truck stop at Albuquerque, N. Mex.).**

CHARGE: Between 3–14–61 and 3–25–61, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by each defendant to 1 count.

DISPOSITION: 7–6–62. Grimes—probation for 2 years. The case against McNeil was transferred to W. Dist. Tex. where, on 9–13–62, he was sentenced to 6 months in prison which was suspended.

7123. (F.D.C. No. 46712. S. Nos. 67–822/4 R, 67–826 R, 68–446 R, 18–881 T.)

INFORMATION FILED: 4–6–62, E. Dist. Tex., against **Marshall Miller (employee of a truck stop), Mt. Pleasant, Tex.**

CHARGE: Between 3–16–61 and 8–21–61, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 8–28–62. Sentence of 4 years in prison suspended, and probation for 3 years.

7124. (F.D.C. No. 47865. S. Nos. 20–741 T, 20–743 T, 20–745 T.)

INFORMATION FILED: 8–28–62, S. Dist. Tex., against **Troy T. Sumpter (employee of a truck stop), Huntsville, Tex.**

CHARGE: Between 1–3–62 and 1–30–62, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–7–62. $300 fine, 6 months in prison suspended, and probation for 5 years.

7125. (F.D.C. No. 47308. S. Nos. 17–101 T, 17–105/6 T.)

INFORMATION FILED: 7–23–62, S. Dist. Ohio, against **Milo A. Gooding, t/a Mi Ru Truck Stop, Norton, Ohio, and Shirley Gooding (an employee).**

CHARGE: Between 8–17–61 and 10–6–61, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Milo Gooding to 2 counts and by Shirley Gooding to 1 count.

DISPOSITION: 9–18–62. Milo Gooding—$1,000 fine, 6 months in prison suspended, and probation for 2 years; Shirley Gooding—$300 fine.

7126. (F.D.C. No. 47833. S. Nos. 15–377 T, 15–619 T, 15–640 T, 16–919/20 T.)

INFORMATION FILED: 8–10–62, E. Dist. Ky., against **William A. Gabbard, Newport, Ky.**

CHARGE: Between 10–19–61 and 1–12–62, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–26–62. Imprisonment for 60 days.

7127. (F.D.C. No. 47077. S. Nos. 67–831/3 R, 67–835/7 R.)

INFORMATION FILED: 7–17–62, N. Dist. Tex., against **Mitchell's Phillips 66 Truck Stop (a partnership), Henrietta, Tex., and Albert L. Chadwick and William O. Kilcrease (employees).**

CHARGE: Between 3–8–61 and 5–11–61, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty by the partnership to 4 counts; by Chadwick to 4 counts; and by Kilcrease to 2 counts.

DISPOSITION: 10–8–62. Partnership—$900 fine and probation for 2 years; each individual—probation for 2 years.

7128. (F.D.C. No. 45692. S. Nos. 49–684 P, 49–686 P, 43–364 R.)

INFORMATION FILED: 8–8–61, Dist. Oreg., against **George Lingas (alias Nick Ramano), Portland, Oreg.**

CHARGE: Between 8–13–59 and 4–8–60, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–10–62. Probation for 5 years.

7129. (F.D.C. No. 46645. S. Nos. 1–559 R, 3–148 R.)

INFORMATION FILED: 4–2–62, N. Dist. Ga., against **Marvin Whitehead (a partner in the S–O Truck Stop), near Toccoa, Ga.**

CHARGE: Between 4–7–61 and 4–12–61, *tablets containing amphetamine sulfate and dextro-amphetamine sulfate* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–24–62. Defendant sentenced to 12 months in prison.

7130. (F.D.C. No. 47871. S. Nos. 45–793/4 T.)

INFORMATION FILED: 8–31–62, W. Dist. Mo., against **Ronald V. Mink and Wilbur J. Reynolds (garage employees), Springfield, Mo.**

CHARGE: On 6–27–62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–29–62. Both defendants fined $500 and sentenced to 6 months in prison.

7131. (F.D.C. No. 47868. S. Nos. 27–781/3 T.)

INFORMATION FILED: 9–21–62, Dist. Kans., against **George M. Sherman, Wichita, Kans.**

CHARGE: Between 1–8–62 and 1–19–62, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 12–19–62. 1 year in the custody of the Attorney General suspended, and probation for 2 years.

7132. (F.D.C. No. 44955. S. Nos. 72–333/6 P.)

INFORMATION FILED: 3–30–61, E. Dist. S.C., against **Elton Joseph Miller, t/a Lucky's Truck Stop, Yemassee, S.C.**

CHARGE: On 12–13–59, *dextro-amphetamine sulfate tablets, desoxyephedrine hydrochloride tablets,* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–23–61. Sentence of 2½ years in prison.

7133. (F.D.C. No. 47348. S. Nos. 13–721/2 R, 13–726 R.)

INFORMATION FILED: 8–2–62, N. Dist. Ill., against **Norman S. Kaplan, t/a Lathrop Drugs, Chicago, Ill., and Kalman Kadish (pharmacist).**

CHARGE: Between 1–11–61 and 4–28–61, *dextro-amphetamine sulfate tablets* were dispensed twice and *secobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Nolo contendere by Kaplan to 3 counts; by Kadish to 2 counts.

DISPOSITION: 10–11–62. Kaplan—$300 fine, plus costs, and probation for 3 months; Kadish—$200 fine, and probation for 3 months.

7134. (F.D.C. No. 47316. S. Nos. 12–264/5 T.)

INFORMATION FILED: 7–10–62, N. Dist. Ill., against **Myron E. Warner (pharmacist), Chicago, Ill.**

CHARGE: Between 9–26–61 and 9–29–61, *dextro-amphetamine sulfate capsules* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–11–62. $500 fine suspended, and probation for 6 months.

7135. (F.D.C. No. 46660. S. Nos. 78–441/3 R.)

INFORMATION FILED: 4–7–62, E. Dist. Tex., against **Delphine Waller (a medical clinic employee), Waskom, Tex.**

CHARGE: On 3–15–61 and 3–22–61, *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–5–62. $100 fine.

7136. (F.D.C. No. 47315. S. Nos. 46–509 R. 46–541/2 R, 46–662 R. 46–718/19 R.)

INFORMATION FILED: 8–31–62, N. Dist. Ohio, against **Harold G. McMichael, t/a Bus's Truck Stop, Bucyrus, Ohio, and Carl R. McMichael and John D. Agin (employees).**

CHARGE: Between 10–22–60 and 3–9–61, *dextro-amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty by Harold McMichael to 6 counts; by John Agin to 3 counts; and by Carl McMichael to 1 count.

DISPOSITION: 12–10–62. Harold McMichael—$6,000 fine and probation for 1 year; Carl McMichael—$500 fine and probation for 1 year; and John Agin—probation for 1 year.

7137. (F.D.C. No. 44281. S. Nos. 4–139 P, 5–053/6 P.)

INFORMATION FILED: 4–6–60, Dist. Md., against **Philip Vodenos, t/a Timonium Pharmacy, Timonium, Md.**

CHARGE: Between 3–11–59 and 4–22–59, *Dexedrine Sulfate tablets* were dispensed 5 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 4–17–61. At the conclusion of the trial on 4–18–61, the jury was unable to agree upon a verdict and was discharged. The case was retried, beginning on 4–9–62, and was concluded with the return by the jury of a verdict of not guilty, on 4–11–62.

7138. (F.D.C. No. 47065. S. No. 54–700 R.)

INFORMATION FILED: 5–29–62, Dist. Minn., against **Olivia Drug Co. (a corporation), Olivia, Minn., and Eric A. Blauert (pharmacist).**

CHARGE: On 6–23–61, *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–20–62. Each defendant fined $250.

7139. (F.D.C. No. 47855. S. Nos. 6–845 T, 6–846 T, 6–851 T, 6–852 T, 7–954 T.)

INFORMATION FILED: 9–13–62, Dist. R.I., against **John P. DePasquale, t/a DePasquale's Pharmacy, Providence, R.I., and James Paola (pharmacist).**

CHARGE: Between 2–14–62 and 3–6–62, *Dexedrine Sulfate tablets* and *secobarbital sodium capsules* were each dispensed twice and *Dexamyl tablets* were dispensed once upon requests for a prescription refill without authorization from the prescriber.

PLEA: Guilty by DePasquale to 4 counts of the information; and by Paola to 3 counts.

DISPOSITION: 10–19–62. DePasquale—$1,000 fine; Paola—$600 fine.

7140. (F.D.C. No. 47351. S. Nos. 32–157 R, 60–294/8 R, 60–300 R, 60–923/7 R.)

INFORMATION FILED: 8–14–62, N. Dist. Ala., against **Goidel Drug Store (a partnership), Decatur, Ala.**

CHARGE: Between 12–13–60 and 3–27–61, *Dexedrine Sulfate tablets* were dispensed 7 times and *Equanil tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *Dexamyl tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–5–62. $250 fine.

7141. (F.D.C. No. 46708. S. No. 60–562 R.)

INFORMATION FILED: 4–12–62, N. Dist. Ala., against **Roy D. Clifton, t/a Ideal Drug Co., Sylacauga, Ala.**

CHARGE: On 1–20–61, *Miltown tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–16–62. $250 fine.

7142. (F.D.C. No. 47366. S. Nos. 1–069 T, 1–076 T, 1–091 T, 1–094 T, 1–098 T.)

INFORMATION FILED: 8–14–62, N. Dist. Ga., against **James Earl Simpson, t/a Simpson Drug Co., Buford, Ga.**

CHARGE: Between 12–3–61 and 1–23–62, *Miltown tablets* were dispensed 4 times and *Equanil tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9–24–62. $50 fine.

7143. (F.D.C. No. 47343. S. Nos. 6–201/3 T, 6–293/4 T, 70–744/8 R, 80–667 R, 81–517 R.)

INFORMATION FILED: 8–17–62, Dist. Mass., against **Anthony A. Contarino, t/a Contarino's Pharmacy, Methuen, Mass.**

CHARGE: Between 6–1–61 and 9–8–61, *Miltown tablets* were dispensed 7 times, *Meticorten tablets* were dispensed 3 times, *Librium Hydrochloride capsules* and *Achromycin capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–8–62. $2,500 fine, 1 year in prison suspended, and probation for 2 years.

7144. (F.D.C. No. 47856. S. Nos. 56–685/9 T.)

INFORMATION FILED: 9–12–62, E. Dist. Tex., against **Harry C. Ward, Sr. (pharmacist), Klondike, Tex.**

CHARGE: On 1–31–62, *Chloromycetin capsules* were dispensed twice, and *hydrocortisone tablets*, *Dexedrine Spansule capsules*, and *penicillin tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–5–62. $500 fine.

7145. (F.D.C. No. 46689. S. Nos. 86–181/5 R, 86–187 R.)

INFORMATION FILED: 2–27–62, E. Dist. Tex., against **John Clifton Bramlett, t/a Bramlett's Pharmacy, Texarkana, Tex., and Tillman E. Ethridge (pharmacist).**

CHARGE: Between 4–18–61 and 5–9–61, *penicillin tablets* were dispensed 3 times, and *meprobamate tablets*, *Dexedrine Sulfate tablets*, and *prednisone tablets* were each dispensed once without a prescription.

PLEA: Guilty by Ethridge to 3 counts and by Bramlett to 4 counts.

DISPOSITION: 3–12–62. Ethridge—fined $300, given a sentence of 6 months in jail which was suspended, and placed on probation for 2 years. 10–15–62. Bramlett—fined $400 and given a sentence of 6 months in jail which was suspended for 1 year, conditioned upon good behavior with active probation.

7146. (F.D.C. No. 47866. S. Nos. 20–387 T, 20–389/94 T.)

INFORMATION FILED: 9–6–62, E. Dist. Tex., against **Manton M. Miller, t/a Miller's Pharmacy, Cooper, Tex.**

CHARGE: Between 1–15–62 and 2–5–62, *penicillin tablets* were dispensed 4 times, *cortisone acetate tablets, hydrocortisone tablets,* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–5–62. $700 fine.

7147. (F.D.C. No. 47846. S. Nos. 57–444/56 T, 70–937/8 T.)

INFORMATION FILED: 8–20–62, N. Dist. Okla., against **James A. Nolen, t/a Radium Springs Sanitorium, Salina, Okla.**

CHARGE: Between 3–15–62 and 4–12–62, *penicillin G potassium tablets* and *methyltestosterone tablets* were each dispensed 3 times; *rauwolfia serpentina tablets, Sulfid B–A tablets, Desoids tablets,* and *Orinase tablets* were each dispensed twice; and *desoxyephedrine hydrochloride tablets* were dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 10–23–62. $6,000 fine and 3 years probation.

7148. (F.D.C. No. 47345. S. Nos. 22–613 R, 24–135 R.)

INFORMATION FILED: 8–22–62, W. Dist. Mo., against **Arthur C. Prewitt, t/a Prewitt Drug Store, Kansas City, Mo.**

CHARGE: Between 4–4–61 and 4–8–61, *penicillin tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–2–62. $300 fine.

7149. (F.D.C. No. 47349. S. Nos. 1–735 R, 45–981 R, 75–002 R, 75–011/12 R, 75–014/15 R.)

INFORMATION FILED: 8–9–62, W. Dist. N.C., against **James T. Hough, Sr., t/a Independence Drug Store, Charlotte, N.C.**

CHARGE: Between 3–3–61 and 5–2–61, *penicillin G potassium tablets* were dispensed 4 times, *Dexedrine Sulfate tablets* were dispensed twice, and *Metandren tablets* were dispensed once without prescriptions.

PLEA: Guilty.

DISPOSITION: 10–9–62. $500 fine, 18 months in prison suspended, and probation for 3 years.

7150. (F.D.C. No. 46704. S. Nos. 54–406/8 R.)

INFORMATION FILED: 10–18–62, W. Dist. Wis., against **Jerome H. Stieber, t/a Stieber Walgreen Agency Drugs, Marathon, Wis.**

CHARGE: Between 5–5–61 and 5–17–61, *Pentids tablets, Equanil tablets,* and *Dexedrine Sulfate tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–13–62. $400 fine.

7151. (F.D.C. No. 47896. S. Nos. 56–804 T, 56–818 T.)

INDICTMENT RETURNED: 9–25–62, N. Dist. Tex., against **Need H. McGown (pharmacist and drug store manager), and Clyde Wayne Carpenter (pharmacist and assistant manager), University Park, Tex.**

CHARGE: Between 2–13–62 and 3–12–62, *pentobarbital sodium suppositories* were dispensed once by McGown upon request for a prescription refill without obtaining authorization from the prescriber, and *triamcinolone tablets* were dispensed once by Carpenter without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–21–62. McGown—$300 fine; Carpenter—$300 fine.

7152. (F.D.C. No. 46699. S. Nos. 7–875/77 R, 66–748 R, 70–183/4 R.)

INFORMATION FILED: 4–4–62, Dist. R.I., against **McCaffrey's, Inc., Providence, R.I., William H. McCaffrey (president), and Eugene M. McCaffrey (secretary-treasurer).**

CHARGE: Between 2–3–61 and 2–21–61, *pentobarbital sodium capsules* were dispensed 3 times, *dextro-amphetamine sulfate tablets* were dispensed twice, and *secobarbital sodium capsules* were dispensed once upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty by the corporation to 5 counts and by the individuals to 3 counts each.

DISPOSITION: 9–21–62. Corporation—$500 fine; each individual—$300 fine.

7153. (F.D.C. No. 47888. S. Nos. 5–710/13 T.)

INFORMATION FILED: 9–6–62, W. Dist. Va., against **Ernest E. Cline, t/a Deadeye's Grill & Truck Stop, Glade Spring, Va.**

CHARGE: Between 3–16–62 and 3–23–62, *methamphetamine hydrochloride tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–19–62. $1,000 fine and 5 years probation.

7154. (F.D.C. No. 43673. S. Nos. 45–202 P, 45–204 P, 45–206 P, 45–208 P, 45–214 P.)

INFORMATION FILED: 11–5–59, Dist. Utah, against **Stanley Bennion, t/a Bennion Drug, Roy, Utah, Fred A. Brink (pharmacist), and Frank S. Hopkin (pharmacist).**

CHARGE: Between 10–15–58 and 11–25–58, *Seconal Sodium capsules* were dispensed 4 times (counts 1–4) upon request for a prescription refill without obtaining authorization from the prescriber, and *Obocell tablets* (count 5) were dispensed once without a prescription.

PLEA: Guilty by Bennion to counts 1, 2, 4, and 5; by Brink to count 2; and by Hopkin to counts 3 and 5.

DISPOSITION: 12–7–59. Bennion—$3,000 fine, probation for 2 years, and suspended sentence of 6 months and 1 day imprisonment; Brink—$400 fine; and Hopkin—$800 fine.

7155. (F.D.C. No. 47832. S. Nos. 3–703/4 T, 3–706 T, 3–709 T, 3–712 T.)

INFORMATION FILED: 8–22–62, S. Dist. W. Va., against **John L. Henderson (a hotel porter), Charleston, W. Va.**

CHARGE: Between 10–5–61 and 11–3–61, *secobarbital sodium capsules* were dispensed twice and *phenobarbital tablets* and *pentobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–14–62. Imprisonment for 1 year.

7156. (F.D.C. No. 47097. S. Nos. 4–598/9 R, 64–952/3 R.)

INFORMATION FILED: 6–12–62, E. Dist. Va., against **Ingram Pharmacy, Inc., Virginia Beach, Va.**

CHARGE: Between 6–3–61 and 8–9–61, *Butazolidin tablets* and *cortone acetate tablets* were each dispensed twice upon request for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 11–12–62. $1,000 fine.

7157. (F.D.C. No. 47113. S. Nos. 75–681 R, 76–198 R, 613 T, 1–205 T, 1–209 T, 1–211 T.)

INFORMATION FILED: 5–28–62, S. Dist. Ga., against **Carl Simmons Ellis, t/a Ellis Drug Store, Nahunta, Ga.**

CHARGE: Between 7–18–61 and 10–25–61, *Equanil tablets* were dispensed 5 times and *Miltown tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7–27–62. $250 fine and probation for 5 years.

7158. (F.D.C. No. 47864. S. Nos. 20–099 T, 20–726 T, 56–582/3 T.)

INFORMATION FILED: 9–19–62, W. Dist. Tex., against **Carl Holzschuher and Walter E. Martin (pharmacists), Alamo Heights, Tex.**

CHARGE: Between 1–22–62 and 2–7–62, *Gantrisin tablets* and *Dexedrine Spansule capsules* were each dispensed twice upon request for prescription refills without authorization from the prescriber.

PLEA: Guilty by each defendant to 2 counts.

DISPOSITION: 9–19–62. Each defendant—$200 fine.

7159. (F.D.C. No. 47341. S. Nos. 31–121/8 R.)

INFORMATION FILED: 8–14–62, N. Dist. Ala., against **John A. Thomas, t/a P & J Pharmacy, Albertville, Ala.**

CHARGE: Between 1–26–61 and 3–22–61, *prednisone tablets* were dispensed 4 times, *Dexedrine Sulfate tablets* were dispensed twice, and *Benzedrine Sulfate tablets* and *Syndrox tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–5–62. $250 fine.

7160. (F.D.C. No. 46014. S. Nos. 10–296/300 R, 10–983 R, 10–986/90 R, 10–992 R.)

INFORMATION FILED: 8–16–61, W. Dist. Pa., against **Broad's Pharmacy, Inc., Wilkinsburg, Pa., Louis Broad (president-pharmacist), and August Pusateri (pharmacist).**

CHARGE: Between 1–14–61 and 3–22–61, *Seconal Sodium capsules* were dispensed 3 times, and *Placidyl capsules, dextro-amphetamine sulfate tablets, apiol and ergot capsules*, and *penicillin tablets* were each dispensed once with-

out a prescription, *Obocell tablets* were dispensed 4 times, and *Butazolidin tablets* were dispensed once upon requests for prescription refills without the authorization of the prescriber.

PLEA: Guilty by Broad and the corporation to all counts; nolo contendere by Pusateri to 2 counts.

DISPOSITION: 3–19–62. Broad—$600 fine and 1 year in prison; corporation—$1,200 fine. 8–6–62. Pusateri—$200 fine, plus court costs, suspended jail sentence, and probation for 3 years.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 7121 TO 7160

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (7137) Prosecution contested.

[1] (7137) Prosecution contested.

U.S. GOVERNMENT PRINTING OFFICE: 1963

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7161–7220

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or, in one case, judgment by the court, and in which, in one case, a decree of dismissal was entered upon motion of the claimant; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere and, in one case, upon a judgment of guilty after trial by the court; and (3) injunction proceedings terminated upon the entry of permanent injunctions by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *November 7, 1963.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 7164, 7165, 7170; an imitation of, and sale under name of, another drug, Nos. 7192, 7193; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7165, 7170; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7162, 7164, 7165, 7171, 7184, 7200, 7201.

707–164—63——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 7161–7220

Adulteration, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

7161. Hematinic tablets. (F.D.C. No. 46072. S. No. 55–875 R.)

QUANTITY: 39 btls. of 90 tablets each, and 18 btls. of 210 tablets each, at Seattle, Wash.

SHIPPED: 2–16–59 and 3–17–60, from Los Angeles, Calif.

LABEL IN PART: (Btl.) "90 [or "210"] Tablets Hematinic for Nutritional Iron Deficiency Anemia Contains: Vitamin Concentrates, Pure Vitamins and Minerals and Vitamin B_{12} with Intrinsic Factor Concentrate * * * In Iron Deficiency Anemia, six tablets are suggested to be taken daily for several weeks * * * Three (3) tablets daily contain * * * Folic Acid 0.4 Milligram."

LIBELED: 7–13–61, W. Dist. Wash.

CHARGE: 502(j)—while held for sale, the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling, since under the label directions for use for iron

deficiency anemia, the article would supply 0.8 milligrams of folic acid per day.

DISPOSITION: 2–12–62. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7162. Various prescription drugs. (F.D.C. No. 46075. S. Nos. 82–812/20 R, 82–835/7 R.)

QUANTITY: 49 ctns., containing approximately 7,734 units, at Mount Vernon, N.Y., in possession of Argus Surgical Supply Co.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Complimentary Dispensing Vial for Physician's Bag," "Professional Sample," "Sample: Not to Be Sold," "Physician's Professional Package," "Complimentary Package," "Professional Sample Not To Be Sold," "Professional Sample—Not For Sale," "Professional Package," and "Physician's Sample—Not To Be Sold."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs which had not yet been repacked, originally intended for use as samples, and still in original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of New York, and quantities of prescription drugs which had been repacked into containers bearing labels which, in some cases did not contain, and in other cases did contain, the names and addresses of manufacturers, packers, or distributors, and which bore such brand names for the drugs as were indicative of their manufacture outside the State of New York. Some of the repacked drugs also bore sample legends; some of the drugs were antibiotic drugs for which certification was prescribed; and some were new drugs.

LIBELED: 7–12–61, S. Dist. N.Y.; amended libel on or about 12–19–61.

CHARGE: Original libel, 502(a)—while held for sale, the statements "Complimentary Dispensing Vial for Physician's Bag," "Professional Sample," "Sample: Not To Be Sold," "Physician's Professional Package," "Complimentary Package," "Professional Sample Not To Be Sold," "Professional Sample—Not For Sale," "Professional Package," "Physician's Sample—Not To Be Sold," and similar wording borne on the labels of said articles were false and misleading as applied to articles then in possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale samples" for physicians and others lawfully engaged in dispensing prescription drugs.

Amended libel, 502(a)—while held for sale, the labeling of some of the articles was misleading as applied to articles which were not suitable for use after their expiration date had expired; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use after their expiration date; 502(l)—some of the articles were represented as drugs composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or a derivative thereof, and they were not from a batch with respect to which a certificate or release was effective since the drugs had passed their expiration dates; 502(f)(1)—the labels of the repacked articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug as required by regulations; 502(b)(1)—the labels of some of

the repacked articles failed to bear the name and place of business of the manufacturer, packer, or distributor; 503(b)(4)—some of the repacked articles were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."; and 505(a)—some of the repacked articles were new drugs which may not be introduced or delivered for introduction into interstate commerce under the provisions of 505(a), since applications filed pursuant to 505(b) were not effective with respect to such drugs.

DISPOSITION: On 8–7–61, Philip A. Lombardi and Albert A. Simon, t/a Argus Surgical Supply Co. and Wesco Drug Co., filed an answer and claim to the drugs. On 10–2–61, the Government filed written interrogatories; on 10–25–61, claimants' motion for summary judgment and the Government's motion for post seizure samples came on to be heard by the court; and on 10–30–61, the Government's motion for post seizure samples was granted.

On 12–8–61, the court denied the claimants' motion for summary judgment and rendered the following opinion:

METZNER, *District Judge:* "Libellant, alleging that containers of drugs are misbranded, has seized the containers and their contents, pursuant to 21 U.S.C. § 334.

"The libel states that the articles of drug are packaged with labels indicating that they are complimentary packages, with such words as 'Professional Sample,' 'Physican's Sample–Not To Be Sold,' etc. It further alleges that these articles are in the possession of a repacker and intended for sale and not intended for complimentary use. It is charged that this is a misbranding within the meaning of 21 U.S.C. § 352(a). That section reads as follows:

> A drug or device shall be deemed to be misbranded—
> (a) If its labeling is false or misleading in any particular.

"The claimants move for summary judgment on the ground that possession of these drugs is not illegal, that the drugs seized were in the original containers and that it is permissible for a pharmacist to use the drugs in such containers for filling prescriptions.

"The claimants are licensed pharmacists in the State of New York and own and operate a drugstore in Mt. Vernon. They rely upon a leaflet issued by the Food and Drug Administration in 1960 (FDA Leaflet No. 12), which, in answer to a question as to what the pharmacist may do with sample packages, states:

> He can, of course, give them to physicians; or he can keep them in the original manufacturer's package and use them in filling prescriptions.

"The position of the government is simply that the drugs are mislabeled if they are intended for sale despite the legend on the labels. It relies solely on the wording of section 352(a), quoted above, and makes no reference to the other subdivisions of that section. The government has not cited any case in which the alleged false statement referred to any fact other than one affecting the characteristics of the product itself.

"The question presented, therefore, is what is the purpose of the 'Not For Sale' legend. This question cannot be resolved on the papers before the court. Accordingly, the motion is denied. So ordered."

On or about 12–19–61, the libel was amended to include additional charges and the prayer of the libel was also amended to include an alternative prayer that, if any of the articles were not in violation of the Act, the claimants be enjoined from repacking the drugs, and be enjoined to limit distribution of the drugs to lawful distributors of prescription drugs in the intact original manufacturer's packages. On or about 2–21–62, the claimants filed an answer to the amended libel. On 2–26–62, the claimants served a copy of their answers to libellant's written interrogatories. On 6–7–62, the court granted the Gov-

ernment's motion to compel further and more complete answers to the interrogatories and ordered that, unless claimants served and filed responsive answers to some 22 enumerated interrogatories of the Government within 7 days of the date of the order, the claimants' answer to the amended libel would be stricken and leave would be given to the Government to enter a decree by default. On 6–20–62, the claimants having consented, a final decree of condemnation was filed and, in accordance with the decree, the drugs were destroyed.

7163. Imitation Diuril tablets. (F.D.C. No. 45693. S. No. 31–662 R.)

INDICTMENT RETURNED: 6–22–61, S. Dist. Tex., against William L. (Tex) Palmer, Sr., t/a Palmer & Co., Houston, Tex., and William L. (Bill) Palmer, Jr., employee.

SHIPPED: 8–4–60, from Houston, Tex., to Marrero, La.

CHARGE: 505(a)—the article was a new drug within the meaning of the law and no application pursuant to 505(b) was effective.

PLEA: Guilty.

DISPOSITION: 2–27–62. "Tex" Palmer, Sr.—$1,000 fine suspended, 6 months imprisonment, and probation for 5 years. "Bill" Palmer, Jr.—one year imprisonment and $1,000 fine, both suspended, and probation for 5 years.

7164. Hydrochlorothiazide. (F.D.C. No. 45971. S. No. 36–500 R.)

INFORMATION FILED: 7–6–61, Dist, N.J., against Kasal Trading Co., a partnership, Englewood, N.J., and Caesar Bottone, partner.

SHIPPED: 9–2–60, from Englewood, N.J., to Philadelphia, Pa.

RESULTS OF INVESTIGATION: The four drums of *hydrochlorothiazide* involved in the case had been imported from Italy by Kasal Trading Co. At the time of entry into the United States, the invoice declared the drums to contain procaine hydrochloride, a drug more commonly known as novocain. The importer of record was listed as "Neo-Quest Chemical Co., Philadelphia, Pa." On 6–26–60, the four drums were shipped by Kasal Trading Co., to Neo-Quest Chemical Co., but subsequently were returned to Kasal Trading Co., Englewood, N.J.

On 9–1–60, a United States Customs agent and a Food and Drug inspector visited the defendants to inquire as to the location of the drug and to advise them that the drug was *hydrochlorothiazide* and not procaine hydrochloride, as it was declared to be. On the next day, the drug was again shipped to Philadelphia, Pa. The shipping clerk of the receiving firm in Philadelphia stated that, from the appearance of the labels on the drums received then, it appeared that portions of the labels had been scraped off with a knife.

CHARGE: Count I, 502(b)(1)—when shipped, on 9–2–60, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Count II, 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to 505(b) was not effective with respect to such drug.

PLEA: Not guilty.

DISPOSITION: On 6–15–62, the case came on for trial before the court. On 6–19–62, the court found the defendants guilty and, on 6–28–62, the individual defendant was fined $500 and placed on probation for 2 years; imposition of sentence was suspended with regard to the partnership.

7165. Meprobamate tablets. (F.D.C. No. 47446. S. No. 39–462 T.)

QUANTITY: 164 cases, each containing 12 unlabeled 500-tablet btls., at New York, N.Y.

SHIPPED: Between 9–13–61 and 3–30–62, from New Jersey.

LABEL IN PART: (Case) "500 Meprobamate Tablets 400 mg."

RESULTS OF INVESTIGATION: The tablets had been manufactured at Jersey City, N.J., from meprobamate powder which had been shipped from Denmark; offered for entry into the United States, on 8–30–61; refused admission, on 9–13–61; and thereafter transported to Jersey City, N.J.

LIBELED: 4–16–62, S. Dist. N.Y.

CHARGE: 502(b)—when shipped and while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the article failed to bear a label containing the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement; 503(b)(4)—the article was a drug subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 5–15–62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE*

7166. Penicillin and streptomycin (combination) injection. (F.D.C. No. 47925. S. No. 32–900 T.)

QUANTITY: 1,095 individually ctnd. 10-cc. vials at Los Angeles, Calif., in the possession of B&B Laboratories, Inc.

SHIPPED: The active ingredients, penicillin and streptomycin, were shipped on unknown dates from Connecticut and/or New York and the final product, as manufactured at Los Angeles, Calif., was delivered to the dealer on or about 1–28–62.

LABEL IN PART: "Multiple Dose Sterile Vial Combination PENICILLIN & STREPTOMYCIN * * * For Intramuscular Injection only * * * Exp. Date: Feb. 1965 * * * Distributed by B&B Laboratories, Los Angeles, Calif."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to meet the standards for strength which were in effect on the date of the certificate. The streptomycin potency was found to be 88.2 percent of the labeled declaration, and a minimum of 90 percent is required. The change which had occurred

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*See also No. 7162.

was not unavoidable in good storage practice since the label instructions were to store the article at 35 to 50 degrees Fahrenheit, and the lot was found to be stored at room temperature of approximately 65 to 70 degrees Fahrenheit.

LIBELED: 7–31–62, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess: and 502(l)—the article was composed in part of penicillin and streptomycin and it was from a batch with respect to which a certificate had been issued pursuant to 507, which certificate had ceased to be effective since the article failed to meet the standards of strength which were in effect on the date of certification.

DISPOSITION: 8–30–62. Default—destruction.

7167. Various prescription drugs. (F.D.C. No. 46441. S. Nos. 1–404/16 T.)

QUANTITY: Approximately 500 pkgs. at Albany, Ga., in possession of U-Save-It Prescription Shop.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample," "Professional Sample," and "Complimentary."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs repacked by the dealer from physicians' samples into bottles to which had been affixed labels bearing the brand names of the drugs, sample legends, and the names and addresses of the manufacturers, packers, or distributors located outside the State of Georgia; some of the articles were prescription drugs which had not at the time the articles were libeled, been repacked by the dealer and whose labels bore sample legends and the names and addresses of manufacturers, packers, or distributors located outside the State of Georgia: and some of the articles consisted of prescription drugs which had been repacked by the dealer into bottles to which had been affixed labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Georgia, but which did not contain identifying lot or control numbers, or the statement "Caution: Federal law prohibits dispensing without prescription."

LIBELED: 9–11–61, M. Dist. Ga.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Physician's Sample," "Complimentary," and similar wording on the labels of a number of the articles, were false and misleading as applied to these articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labels of a number of the articles failed to bear adequate directions for use, and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug as required by regulations; 503(b)(4)—a number of the articles were drugs subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."; and 502(l)—an article of drug, labeled in part "Achromycin V," was a drug composed in part of a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate was effective since the drug had passed its effective expiration date.

DISPOSITION: 12–7–61. Default—destruction.

DRUG FOR VETERINARY USE

7168. Medicated feeds. (F.D.C. No. 45656. S. Nos. 7-045/6 R, 8-872 R.)

INFORMATION FILED: 8-15-61, N. Dist. N.Y., against Elmore Milling Co., Inc., Oneonta, N.Y.

SHIPPED: Between 10-13-59 and 4-13-60, from Oneonta, N.Y., to Fairfield, Vt., and Orange, Mass.

LABELS IN PART: (Bag tags) "100 Lbs. Net Medicated For the prevention of cecal and intestinal coccidiosis and growth stimulation, improved food efficiency and pigmentation in chickens. Feed continuously as the only ration. Active Drug Ingredient(s) Sulfaquinoxaline—.0150% Arsanilic Acid—0.01% Ingredients Wheat Standard Middlings, Soybean Oil Meal, Meat and Bone Scraps * * * Analysis Min. Crude Protein 20% Min. Crude Fat 3% Max. Crude Fiber 5% Manufactured by Elmore Milling Company, Inc. Oneonta, New York Elmore Chixsaver"; "100 Lbs. Net Medicated For increasing egg production and improving feed efficiency. Feed continuously as the only ration. Active Drug Ingredient(s) Arsanilic Acid—0.01% Ingredients Wheat Standard Middlings, Soybean Oil Meal, Meat and Bone Scraps * * * Analysis Min. Crude Protein 16% Min. Crude Fat 4% Max. Crude Fiber 5% Manufactured by Elmore Milling Company, Inc. Oneonta, New York * * * Elmore Complete Market Egg Ration (1A)"; and "100 Lbs. Net Medicated For growth stimulation in chickens. Feed continuously as the only ration. Active Drug Ingredient(s) 3-Nitro-4 Hydroxyphenylarsonic Acid—0.005% Ingredients Wheat Standard Middlings, Soybean Oil Meal, Meat and Bone Scraps * * * Analysis Min. Crude Protein 16% Min. Crude Fat 4% Max. Crude Fiber 5% Manufactured by Elmore Milling Company, Inc. Oneonta, New York Elmore Complete Market Egg Ration (1A)."

CHARGE: *Elmore Chixsaver*, 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess, in that it contained more sulfaquinoxaline and more arsanilic acid than represented namely, approximately 180 percent of the represented amount of sulfaquinoxaline and approximately 209 percent of the represented amount of arsanilic acid; and 502(l)—the article was a drug composed in part of bacitracin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

Elmore Complete Market Egg Ration (active ingredient—arsanilic acid), 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess in that it contained less arsanilic acid than represented, namely, approximately 75% of the represented amount of arsanilic acid.

Elmore Complete Market Egg Ration (active drug ingredient 3-nitro-4 hydroxyphenylarsonic acid), 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess in that it contained less than 0.005 percent 3-nitro-4 hydroxyphenylarsonic acid, namely, approximately 36 percent of the represented amount of 3-nitro-4 hydroxyphenylarsonic acid.

The information alleged also that another article, namely, Elmore Hog Ration, was adulterated under the provisions of the law applicable to food, as reported in the notices of judgment on foods.

PLEA: Guilty.

DISPOSITION: 12-6-61. $600 fine on the charges involving drugs; $750 total fine.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7169. Multiglands injection, Dialen chewing gum, and Geralen tablets. (F.D.C. No. 44201. S. Nos. 79–104 P, 79–106/7 P.)

QUANTITY: 80 30-cc. btls. of *Multiglands injection*, 12 btls., each containing 500 tablets of *Dialen chewing gum*, and approximately 800 tablets of *Geralen*, at Detroit, Mich., in possession of Len-Tag & Co.

SHIPPED: The *Multiglands injection* was shipped between 6–18–59 and 6–25–59, from Philadelphia, Pa.; the *Dialen chewing gum* was shipped on 7–3–58, from Long Island, N.Y.; and the *Geralen tablets* were shipped on 8–8–58, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "30 cc. Multiple Dose Vial List No. 334 Multiglands (Plurigland Extract) Intramuscular Only * * * Distributed by Len-Tag & Company, Detroit 12, Mich. Control: 031709 Each 2 cc. represents the water soluble extraction of dried glands derived from: Suprarenal Cortex, fresh gland 3.0 grs. Thyroid, fresh gland 2.0 grs. Pituitary Anterior, fresh gland 1.0 grs. Pituitary Posterior, fresh gland 0.1 grs. Ovarian Substance, fresh gland 15.0 grs. Thymus, fresh gland 3.0 grs. Lymphatic, fresh gland with Chlorobutanol (Chloral derivative) 0.5% Benzyl Alcohol 1.0%"; "500 Len-Tag No. 3013 Dialen (Phenylpropanolamine Hydrochloride) Chewing Gum 25 Mgm. Tablets Distributed by Len-Tag & Co. Detroit 12, Mich. Each chewing gum tablet contains Phenylpropanolamine hydrochloride 25 mgm."; and "100 S.C. Yellow Len-Tag No. 806 Geralen (Capsule-Shaped) Tablets Geriatrics & Stress Formula 17729 Distributed by Len-Tag & Co. Detroit 12, Mich. Each Sugar Coated Tablet Contains: Methyl Testosterone 2.5 mg."

LIBELED: 1–28–60, E. Dist. Mich.

CHARGE: *Multiglands injection*, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as an aid in reducing diets and as an appetite depressant; and 502(f)(1)—the article failed to bear adequate directions for use.

Dialen chewing gum, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as an aid in reducing diets and as an appetite depressant.

Geralen tablets, 502(a)—while held for sale, the labeling of the article contained the false and misleading statement "Geriatrics and Stress Formula"; and 503(b)(4)—the article was a drug subject to 503(b)(1)(B) because it contained methyltestosterone, and its label failed to bear the statement "Federal law prohibits dispensing without prescription."

DISPOSITION: 3–8–60. Default—destruction.

7170. Various drugs. (F.D.C. No. 42780. S. Nos. 28–457/64 P.)

QUANTITY: 72 1-oz. tubes of *Bichon's rectal ointment;* 1 1-gal. btl., 33 8-oz. btls., and 17 4-oz. btls. of *Bichon's Sanative Wash;* 30 1-lb. tins and 8 tins of *Bichon's White Healing Salve;* 30 1-lb. jars and 7 jars of *Bichon's Triple Strength Salve;* 4 1-gal. btls. and 11 4-oz. btls. of *Bichon's Asma;* 6 1-gal. btls., 8 8-oz. btls., and 23 4-oz. btls. of *Bichon's Syrup Calcium Iodide;* 3 1-gal. btls. and 16 4-oz. btls. of *Tritica;* and 7 1-gal. btls. and 25 8-oz. btls. of *Bichon's T.W.*, at Houston, Tex., in possession of Bichon Drug Store.

SHIPPED: Between 9–5–57 and 11–7–58, from St. Louis, Mo., Indianapolis, Ind., Saratoga Springs, N.Y., and Bristol, Tenn.

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*See also Nos. 7162, 7164, 7165, 7167.

LABEL IN PART: (Tube and ctn.) "Bichon's Rectal Ointment * * * Benzocaine, Zinc Oxide, Powd. Ext. Witchhazel, Camphor, Thymol, Menthol, Chaulmoogra Oil, Colloidal Kaolin, Petrolatum. For prompt relief of the burning, itching, and the irritation associated with hemorrhoids (piles) No. 171 Bichon Drug Co."; (btl.) "Bichon's Sanative Wash * * * As a Douche Twice Daily Distributed by Bichon Drug Co."; (tin) "Bichon's White Healing Salve Sold Only By Bichon Drug Co."; (jar) "Bichon's Triple Strength Salve Active Ingredients: Zinc Oxide, Boric Acid and Eucalyptol Bichon Drug Store * * * Houston, Texas"; (btl.) "Bichon's Asma * * * For the Temporary Relief of the Paroxysms of Asthma and Bronchial Irritations Packed by Bichon Drug Co."; (btl.) "Bichon's Syrup Calcium Iodide Active Ingredient: Calcium Iodide. Recommended by us for the Relief of the Conditions for which this special treatment is needed. * * * Made and sold by Bichon Drug Co."; (btl.) "Bichon's Tritica * * * Active Ingredient: Fluidextract Triticum. A Diuretic to the Kidneys to Increase the Urinary Flow. * * * Packed by Bichon Drug Co."; (btl.) "Bichon's T.W. Contains Alcohol 14%, Cascara Sagrada, Viburnum, Opulus, Black Haw, Gelsenium, Passiflora, Squaw Vine, Life Root and Aromatics * * * Distributed by Bichon Drug Store."

ACCOMPANYING LABELING: Leaflets entitled "The Famous Bichon Remedies," and additional repack labels.

RESULTS OF INVESTIGATION: The articles, except the tubes of *rectal ointment*, were shipped in bulk and repacked by the dealer and labeled as described above.

LIBELED: 1–14–59, S. Dist. Tex.

CHARGE: *Rectal ointment*, 502(f)(2)—while held for sale, the labeling of the article failed to warn that it should not be used in case of rectal bleeding, which may indicate serious disease.

Sanative Wash, 502(f)(2)—while held for sale, the labeling of the article failed to warn that it should not be used more than twice weekly unless directed by a physician; and 502(e)(2)—the label failed to bear the common or usual name of the active ingredients contained therein.

White Healing Salve, 502(b)(2)—while held for sale, the label failed to bear an accurate statement of the quantity of contents; 502(e)(2)—the label failed to bear the common or usual name of the active ingredients contained therein; and 502(f)(1)—the labeling failed to bear adequate directions, including indications, for use.

Triple Strength Salve, 502(a)—while held for sale, the labeling, namely, the leaflet, contained false and misleading representations that the article was an adequate and effective treatment for old sores and skin eruptions; 502(b)(2)—the label failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—the label failed to bear the common or usual name of the active ingredients contained therein since Peru balsam and thymol iodide were not declared on the label. *Asma*, 503(b)(4)—while held for sale, the article was a drug subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Syrup Calcium Iodide, 502(f)—while held for sale, the labeling of the article failed to bear (1) adequate directions, including indications for use, and (2) a warning that in case skin rash appears, use of the article should be discontinued and a physician consulted.

Tritica, 502(a)—while held for sale, the labeling, namely, the bottle label and the leaflet, contained false and misleading representations that the article was an adequate and effective treatment for all those conditions due to difficult urination and scanty urine flow.

Bichon's T.W., 502(a)—while held for sale, the labeling, namely, the leaflet, contained false and misleading representations that the article was an adequate and effective treatment for cramping, too much and too little flow associated with the monthly menstrual cycle, and menopause in women.

DISPOSITION: 4–3–59. Consent—claimed by Juliette P. Bichon, t/a Bichon Drug Store. The *rectal ointment*, *Syrup Calcium Iodide*, *Triple Strength Salve*, *Bichon T.W.*, and *White Healing Salve* were relabeled; the *Asma* and *Tritica* were destroyed; and the *Sanative Wash* was converted to nonmedical use. All of the old labels and leaflets were destroyed.

7171. Various prescription drugs. (F.D.C. No. 46772. S. Nos. 13–101/8 T.)

QUANTITY: Various quantities of tablets and capsules at Chicago, Ill., in possession of Weitzman Prescription Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "Complimentary," "Physician's Professional Package," "Professional Sample Not To Be Sold," and "Sample Not To Be Sold."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs repacked by the dealer from physicians' samples into containers which had labels bearing brand names indicative of manufacture outside the State of Illinois; and some of the articles were prescription drugs which were not yet repacked, originally intended for use as samples, and still in their original packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois.

LIBELED: 12–4–61, N. Dist. Ill.

CHARGE: Repacked articles, 502(a)—while held for sale, the statements "Professional Sample," "Complimentary," "Physician's Professional Package," and similar wording on the labels of the articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs, as required by regulations; 502(b)(1)—some of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 503(b)(4)—some of the articles were drugs subject to the provisions of 503(b)(1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Articles not yet repacked, 502(a)—the statements "Professional Sample," "Professional Sample Not To Be Sold," "Sample Not To Be Sold," "Complimentary," and similar wording on the labels of the articles, were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

Articles not yet repacked whose expiration dates had expired, 502(a)—the labeling of the articles was misleading as applied to articles which were not suitable for use after their expiration date had expired; and 502(f)(1)—

the labeling of the articles failed to bear adequate directions for use after their expiration date.

DISPOSITION: 12–29–61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

7172. R.X.–120 tablets. (Inj. No. 354.)

COMPLAINT FOR INJUNCTION FILED: 7–29–59, S. Dist. N.Y., against Wilson-Williams, Inc., Tuckahoe, N.Y., and Jack Elliott, president.

NATURE OF BUSINESS: The defendants were engaged in selling and distributing in interstate commerce, a drug, R.X.–120, which was packaged in various-size bottles and labeled in part as follows: "Tablets R.X.–120 For treatment of Overweight Each Tablet Contains: Phenylpropanolamine HCL 25 mgm. Sodium Caseinate 1 gr. Dextrose 1 gr. WILSON-WILLIAMS, INC. * * * Tuckahoe, N.Y. Sole Distributor. DIRECTIONS: One tablet three times daily with water, thirty to forty-five minutes before each meal to depress appetite. CAUTION: Individuals with hyperthyroidism, hypertension, heart disease or diabetes should use only as directed by physician."

In conducting their business, the defendants employed the following method of operations: 1. Defendants mailed and continued to mail in interstate commerce, the drug, designated as R.X.–120, in packages which also contained leaflets entitled "R.X.–120 FOR TREATMENT OF OVERWEIGHT AND OBESITY," reorder coupons, and business reply envelopes; 2. Various quantities of the drug, in the form of tablets, were manufactured by S. B. Leonardi & Co., at Rye, N.Y., upon instructions of defendants; 3. At the direction of the defendants, the tablets of the drug were packaged and labeled by S. B. Leonardi & Co., and by Bulk Mailing Co., Mount Vernon, N.Y.; 4. The defendants solicited and caused to be solicited, by mail, newspaper, and magazine, orders for the drug, and following the receipt of such orders the defendants caused the drug, packaged and labeled as above, to be distributed throughout the United States; 5. For the purpose of explaining the uses of the drug and promoting its sale and distribution, the defendants caused the drug to be accompanied by certain labeling relating to it, including the following items of written, printed, and graphic matter: (a) Printed sheets headed "Released as Safe by UNITED STATES GOVERNMENT! New doctor prescribed wonder drug does away with all special diets! YOU MUST LOSE UP TO 49 LBS. OR WE PAY YOU $14.00!"; (b) Leaflets reading in part "Dear Friend: How would you like to close your eyes and suddenly find that you have taken off . . . 9 pounds in 10 days! . . . 18 pounds in 20 days! . . . 27 pounds in 30 days! . . . up to 49 pounds in 8 weeks!"; (c) Order blanks to which were attached a guarantee reading in part "Keep This Guarantee * * * FREE TRIAL! YOU MUST LOSE UP TO 49 POUNDS OR WE PAY YOU $14.00." Since June 1958, defendants had ordered, and caused to be produced, in excess of 10,000,000 tablets of R.X.–120, and at the time of filing the complaint, were continuing to order and cause to be produced and to distribute in interstate commerce, large quantities of the drug misbranded in the manner described below.

CHARGE: The complaint alleged that, when shipped in interstate commerce, the drug was misbranded within the meaning of 502(a) in that the labeling of the drug contained false and misleading representations that the drug was capable of causing a person to lose 49 pounds in 8 weeks, 27 pounds in 30 days, 18 pounds in 20 days, 9 pounds in 10 days, and that such weight reduction was

*See also Nos. 7162, 7164, 7165, 7167, 7169–7171.

accomplished without special diet; that the drug had been released as safe by the United States Government; that, until recently, the drug could not be purchased without a doctor's prescription; that the drug was a new wonder drug; that the drug had received the most extensive clinical testing ever devoted to any drug; that the drug depressed the appetite, decreased the desire for food by acting on the central nervous system, fought hunger contractions, and telegraphed a "stop signal" to the brain when one was tempted to overeat or indulge in between-meal snacks; and that the drug was an adequate and effective treatment for overweight and obesity.

The complaint alleged further that the drug was misbranded under 502(f)(1) since the labeling which physically accompanied *R.X.–120* in shipments in interstate commerce, did not bear adequate directions for use by reason of the failure to state the conditions and purposes for which the drug was intended.

DISPOSITION: On 7–31–59, a temporary restraining order was issued by the court enjoining the defendants and all persons in active concert or participation with them from shipping in interstate commerce, *R.X.–120*, or the same article by any other designation, or any similar article which:

(a) Was accompanied by the following written, printed, or graphic matter or accompanied by any written, printed, or graphic matter, substantially to the same effect: Printed sheets headed "Released As Safe"; leaflets entitled "RX–120 FOR TREATMENT OF OVERWEIGHT AND OBESITY"; leaflets reading in part "Dear Friend: How would you like to close your eyes and suddenly find"; and order blanks to which are attached a guarantee reading in part "Keep This Guarantee * * * Free Trial";

(b) Bore or was accompanied by any written, printed, or graphic matter which stated, represented, suggested, or implied that such article was capable of causing a person to lose 49 pounds in 8 weeks, 27 pounds in 30 days, 18 pounds in 20 days, 9 pounds in 10 days, and that such weight reduction was accomplished without special diet; that such article had been released as safe by the United States Government; that until recently such article could not be purchased without a doctor's prescription; that such article was a new wonder drug; that such article had received the most extensive clinical testing ever devoted to any drug; that such article depressed the appetite, decreased the desire for food by acting on the central nervous system, fought hunger contractions, and telegraphed a "stop signal" to the brain when one was tempted to overeat or indulge in between-meal snacks; and that such article was adequate and effective for the treatment of overweight or obesity; or which contained any other false and misleading representations or suggestions; or

(c) Failed to state in its labeling all of the diseases, conditions, symptoms, and purposes for which the article was intended to be used and for which it was represented, by any means, to the public.

On 9–15–59, the court heard argument on the Government's motion for a temporary injunction, and, on 9–22–59, rendered the following opinion:

MURPHY, *District Judge:* "Plaintiff's motion for an injunction *pendente lite* is granted.

"Defendants are engaged in a large mail order distribution of a drug called R.X.–120 for the treatment of overweight. It contains 25 mgm. of phenylpropanolamine. Defendants also distribute through an independent mailing company extensive literature containing many extravagant claims and representations that are both misleading and false. It is clear from the moving papers that defendants have introduced into interstate commerce a misbranded drug and that the mailings, although separate from the drug itself, are nevertheless a part of the labeling of the drug. The text of these statements

tells the public of the rapidity with which R.X.–120 may be expected to treat obesity.

"Although we have some doubt as to whether the label physically attached to the vial that contains the drug makes it a misbranded drug, we are convinced by the proof submitted and not contradicted that the flamboyant literature that accompanies it, or is advertised in connection with it, is false for these statements say:

" 'Released as Safe'; 'RX–120 FOR TREATMENT OF OVERWEIGHT AND OBESITY'; 'Dear friend: How would you like to close your eyes and suddenly find . . .'; 'Keep This Guarantee'; and in substance that such article (RX–120) is capable of causing a person to lose 49 pounds in 8 weeks, 27 pounds in 30 days, 18 pounds in 20 days, 9 pounds in 10 days, and that such weight reduction is accomplished without special diet; such article has been released as safe by the United States Government; until recently such article could not be purchased without a doctor's prescription; such article is a new wonder drug; such article has received the most extensive clinical testing ever devoted to any drug; such article depresses the appetite, decreases the desire for food by acting on the central nervous system, fights hunger contractions, and telegraphs a 'stop signal' to the brain when one is tempted to overeat or indulge in between-meal snacks; and such article is adequate and effective for the treatment of overweight or obesity.

"The Government has submitted proof that the tests conducted show that phenylpropanolamine does not possess significant appetite depressant potency.

"In opposition to the overwhelming proof submitted by the Government, defendant relies on the affidavit of one Dr. Bohensky and a number of articles printed many years ago, the authors of which have by reply affidavit contradicted and withdrawn their endorsements. Significantly the most that Dr. Bohensky does in his affidavit is to state that in his opinion phenylpropanolamine is an effective appetite depressant. Nowhere are there any facts submitted which tend in the least to support the exaggerated claims in defendants' advertisements. It is true that the doctor questions the validity of the tests conducted by the Government and argues with some force that the tests are not significant since the patients were mentally retarded. He points out that phenylpropanolamine acts as an appetite depressant in several ways—it stimulates the sympathetic and central nervous systems by decreasing the hunger sensation and desire for food and, accordingly, would have little or no effect on people whose nervous systems are retarded.

"However, defendants miss the thrust of the Government's complaint. The Government does not bring this action and seek this injunction on the ground that phenylpropanolamine is not an anorexigenic drug. Its complaint is bottomed on the fact that in introducing it into interstate commerce defendants have mislabeled and misbranded it by making exaggerated and false claims which they have not contradicted on this motion.

"From a reading of all of the papers we are convinced that it is likely that plaintiff will ultimately prevail in this action. The urgency of immediate injunction is because the gullible public will be swamped with a misbranded drug long before definitive judgment can be obtained. Defendants' business is such that the manufacture of the pills and the handling and mailing operations are performed by others. It is operated without much capitalization and on a speculative appeal basis.

"Settle order before October 3, 1959."

On 10–2–59, an injunction *pendente lite* was entered enjoining the defendants and all persons in active concert or participation with them from shipping in interstate commerce, *R.X.–120*, or the same article by any other designation or any similar article which bore or was accompanied by the written, printed, or graphic matter as described above at provision (a) and (b) of the temporary restraining order.

On 10–7–59, the Government served written interrogatories on the defendant, Wilson-Williams, Inc. Thereafter, that defendant filed objections to the Government's interrogatories. The defendant objected to all of the Government's interrogatories for the following reasons:

(a) The instant action is not a civil action within the meaning of Rule 1 of the Federal Rules of Civil Procedure, and consequently Rule 33 pertaining to interrogatories, is inapplicable;

(b) The instant action seeks a forfeiture of defendants' property for an alleged violation of a law of the United States, and consequently under Rule 81 of the Federal Rules, Rule 33 pertaining to discovery, is inapplicable; and

(c) Even assuming that Rule 33 is applicable to the instant action, the interrogatories nevertheless should be stricken because they are burdensome, vexatious, oppressive and call for evidentiary minutia unnecessary and irrelevant to the issues involved herein.

The defendant also objected to certain specific interrogatories on additional grounds. On 11–3–59, the defendants filed an answer to the complaint, denying that the article was misbranded.

On 11–25–59, the court issued the following order:

METZNER, *District Judge:* "The United States has brought an action for an injunction to prevent the introduction into interstate commerce of an allegedly misbranded product claimed to be a dietary aid. § 301(a) of the Food, Drug and Cosmetic Act, 21 U.S.C.A. § 332(a). Defendant objects to the interrogatories propounded pursuant to Rule 33 of the Federal Rules of Civil Procedure. The individual defendant has already declined to answer interrogatories, invoking his fifth amendment privilege.

"Aside from the usual objections to interrogatories, the defendant corporation challenges the right of the Government to propound any interrogatories to it on the ground that the Federal Rules of Civil Procedure, particularly Rule 33, are inapplicable in this type of action.

"Two questions are presented: (1) Does the Food, Drug and Cosmetic Act by its terms expressly or impliedly make the discovery rules inapplicable to injunction actions under § 301(a)? (2) Does Rule 1 or 81, or both, make such rules inapplicable to this case?

"It seems clear, in answer to the first question, that there is nothing in the Food, Drug and Cosmetic Act that expressly or impliedly makes the usual discovery procedures inapplicable to a § 301(a) injunction action. To support its argument, defendant corporation relies on the case of *U.S.* v. *Dean Rubber Mfg. Co.* (W.D. Mo. 1947) 72 F. Supp. 819.

"In *Dean Rubber* the question at issue was whether in an action for contempt under § 301(b) for disobedience of an injunction gained under § 301(a), a special one-year statute of limitations in the Clayton Act applied or whether the three-year statute of limitations applicable generally in actions by the Government for contempt governed. Since § 301(b) made the then § 22 of the Clayton Act applicable in regard to the procedure to be followed at the trial, the defendant argued that all other portions of the Clayton Act relating to contempt were applicable as well. The court in holding that the general statute of limitations was applicable rejected this argument, stating:

> In providing that Section 22 of the Clayton Act shall be the procedure to be followed in prosecution of alleged contempts for violation of injunctions procured under the Federal Food, Drug and Cosmetic Act, Congress established a limited special procedure to be followed in such cases and took such contempt actions out of the procedure generally followed 'at law and in equity' in cases wherein the United States was the party procuring an injunction decree or order. *Dean Rubber* at p. 821.

This quotation, when read in the context of the decision, clearly indicates that the words 'limited special procedure' were used by the court to mean that only the special procedure of § 22 of the Clayton Act was to be looked to for deviations from procedure generally followed 'at law and in equity' and not that where § 22 did not specify a deviation it was nevertheless exclusive and barred use of a general rule.

"Moreover we are dealing here with a § 301(a) case, and not a § 301(b) case which was before the court in *Dean Rubber*. § 301(a) provided that the district courts' jurisdiction is subject to the provisions of § 17 of the Clayton Act (28 U.S.C.A. § 381) relating to notice to an opposite party. However, § 17 of the Clayton Act was subsequently repealed and Congress placed its provisions in Rule 65 of the Federal Rules of Civil Procedure so that it is

now a rule general to all injunction suits. Thus it would seem logical to assume that if there was any specific Congressional intent as to the procedure to be followed in § 301(a) actions, it was that the body of Federal Rules within which Congress placed former § 17 of the Clayton Act was applicable.

"Defendant also argues that the inclusion of specific investigatory powers in the Food, Drug and Cosmetic Act (§§ 702, 703 and 704, 21 U.S.C.A. § 372–374), and specifically the grant of immunity from prosecution to those persons required to permit the copying of their records concerning interstate shipments, implies that Congress intended the procedure to be exclusive. § 703 provides, generally, that carriers engaged in interstate commerce and persons receiving food, drugs, or cosmetics in interstate commerce or holding such articles so received must permit the Secretary at reasonable times to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or possession thereof during or after movement, the quantity thereof and the name of the shipper and consignee. It further provides an immunity from criminal prosecution for the person from whom the evidence was obtained. Defendant argues that by permitting the Government to use the discovery procedures in the Federal Rules, the safeguards provided in the Act will be circumvented. In *U.S.* v. *75 Cases* (4 Cir. 1944) 146 F. 2d 124, cert. den., 325 U.S. 856 (1945), the court in interpreting § 703 as to an investigation prior to a libel for condemnation of impure food stated:

> In connection with Section 373 [§ 703] of the Act, there is no ground for the application of the maxim expressio unius est exclusio alterius. We interpret this section, rather as affording a cumulative procedure to the Government, without restricting other avenues of information. (p. 127)

If the Secretary is not bound to use only the specified discovery weapons provided by the Act in an investigation to determine whether the Act has been violated, *a fortiori* there seems to be no reason to believe that Congress intended that the enumerated investigatory powers of the Secretary excluded the Government from use of the discovery procedure under the Federal Rules in a plenary action for an injunction.

"The interrogatories by the Government do not ask for any information which if asked for from defendant under § 703 would furnish an immunity from criminal prosecution. Defendant corporation does not seem to be within the class of persons to whom immunity could be afforded under § 703, since that section refers only to 'carriers engaged in interstate commerce, and persons receiving food, drugs, devices or cosmetics in interstate commerce or holding such articles so received.' The defendant corporation is in the business of selling and distributing R.X.–120 in interstate commerce. Obviously immunity would not extend to the giving of such information by persons other than those enumerated.

"However, as was indicated in *U.S.* v. *75 Cases*, *supra*, the provision in § 703 granting immunity from criminal prosecution was put in to make it easier for the Secretary to carry on his investigatory functions, not to place safeguards in the statute which go beyond those constitutionally required. The statute defines a 'corporation' as a 'person.' Even if defendant corporation were in the protected class and furnished information on the Secretary's request under § 703, it does not follow that Congress intended to grant the corporation immunity or intended to enable the corporation to refuse to divulge such information if another means of gaining the information were pursued. Provisions placed in a regulatory statute to enable an administrator to more easily investigate violations of the statute should not be read unless expressly so stated to restrict the Government from expeditiously enforcing Federal law. *U.S.* v. *75 Cases*, *supra*, p. 127. It is clear that a corporation cannot claim the fifth amendment, *Hale* v. *Henkel* (1906) 201 U.S. 43; Cf. *U.S.* v. *White* (1944) 322 U.S. 694, and this is true even if the question propounded by interrogatory under Rule 33 might tend to incriminate. *U.S.* v. *42 Jars* (D.N.J. 1958) 162 F. Supp. 944, aff'd, (3 Cir. 1959) 264 F. 2d 666. But, although the defendant here admits this to be true, it wishes us to find such a privilege nevertheless by a circumlocutory device. It would read the provisions of the Food, Drug and Cosmetic Act granting the Secretary broad investigatory powers as a limitation on the power of the Government to have the corporation answer questions in a plenary injunction suit brought under that statute.

"The defendant also relies on a broad proposition that administrative investigatory powers provided for in a statute preclude the use of the discovery procedures. In all the cases brought to the court's attention, the action by the administrative body was a summary proceeding and in all those cases the question was raised by the defendant who wished the 'safeguards' of the Federal Rules, such as service of process, and finding of facts and law. In *Goodyear Tire & Rubber Co.* v. *N.L.R.B.* (6 Cir. 1941) 122 F. 2d 450, the court in holding that the Federal Rules were not generally applicable where the N.L.R.B. sought enforcement of a subpoena stated:

> Obviously, if the enforcement of valid subpoenas, the issuance of which is a mere incident in a case, were to require all the formalities of a civil suit, the administrative work of the Board might often be subject to great delay.

The rationale of all of the cases which the defendant cites is to the same effect. None of the cases apply to a proceeding which Congress has chosen to be determined as a plenary matter in the Federal Courts.

"Defendant also argues that Rules 1 and 81 of the Federal Rules of Civil Procedure make the discovery procedures inapplicable to the present case. As to the exception from the rules of actions for 'forfeiture of property for violation of a statute of the United States,' contained in Rule 81(a)(2), it would seem enough to say that 'forfeiture' is a word of art and does not include suits for the enjoining of prospective acts.

"The final argument of defendant is predicated on the wording of Rule 1 of the Federal Rules of Civil Procedure which states that the 'rules govern the procedure in the United States District Courts in all suits of a civil nature.' It is claimed that this proceeding is criminal in nature and therefore bars the application of Rule 33. I disagree with defendant's characterization of this proceeding being criminal in nature. An enforcement procedure, in addition to the one at bar, provided for by the Food, Drug and Cosmetic Act is seizure by condemnation proceedings. § 304(b), 21 U.S.C.A. § 334. It has been held in such proceedings that the Federal Rules of Civil Procedure do apply. *U.S.* v. *5 Cases* (2 Cir. 1950) 179 F. 2d 519, cert. den., 339 U.S. 963. See also *U.S.* v. *75 Cases*, *supra*, at p. 127. In this posture of the law this is not criminal in nature.

"Defendant relies heavily upon *Boyd* v. *U.S.* (1886) 116 U.S. 616. That was an action for forfeiture which was criminal or quasi-criminal in nature. Similarly, in *U.S.* v. *Solomon* (D. Ill. 1944) 3 F.R.D. 411 the action was for a fine or penalty. Even if the defendant here was an individual he could only object to answering specific questions propounded pursuant to Rule 33 on the ground of self-incrimination, but that is different from objecting to the applicability of discovery procedures as such.

DISPOSITION OF OBJECTIONS TO SPECIFIC INTERROGATORIES

"The interrogatories propounded by the Government contain some 450 items in 25 pages. The objections thereto are disposed of as follows:

1. So much of Interrogatory No. 3 is stricken as follows the word 'report' on the last line of Page 1, to the end of the sentence.
2. Interrogatories Nos. 5(D), 5(E), 5(G) through 5(Q), and 5(T) are stricken.
3. I assume that Interrogatories Nos. 6 through 12 relate to the defendant in this action and that the denomination 'Wilson-Williams Corporation' is a typographical error. If not, then Interrogatories Nos. 6 through 12 are stricken. If so, then only Interrogatories Nos. 8, 10 and so much of Interrogatories Nos. 11 and 12 as refers to Interrogatories Nos. 8 and 10 are stricken.
4. Interrogatory No. 15(f) is stricken.
5. Interrogatories Nos. 18(c) through 18(i) are stricken.
6. Interrogatory No. 21 is stricken.
7. Interrogatory No. 22(b) is stricken.
8. Interrogatories Nos. 25(d), 25(e), 25(g) through 25(l), and 25(p) are stricken.

9. Interrogatories Nos. 26(d) and 26(f) through 26(o) are stricken.
10. Interrogatories Nos. 27(b) through 27(n) are stricken.
11. Interrogatories Nos. 34 through 41 are stricken.

"The motion is otherwise denied. Interrogatories are to be furnished on or before December 31, 1959. So ordered."

On 12–31–59, Wilson-Williams, Inc., filed written answers to the Government's interrogatories.

Thereafter, the defendants appealed the order of the district court with respect to the injunction *pendente lite*. On 4–13–60, the United States Court of Appeals for the Second Circuit heard argument and, on 4–27–60, affirmed the district court's order, rendering the following opinion:

PER CURIAM: "The single question presented by this appeal is whether the district court properly exercised its discretion in enjoining, *pendente lite*, Wilson-Williams, Inc., and its president, Jack Elliott, from distributing in interstate commerce a drug called R.X.–120 accompanied by any written, printed, or graphic matter representing that the drug is capable of causing loss of weight without special diet, and other representations which the Government claimed to be false. We find ample support for Judge Murphy's decision and, accordingly, we affirm the order.

"The Government brought suit under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 332(a) alleging that the defendants were distributing in interstate commerce a drug, R.X.–120, which was misbranded in that literature advertising the drug and accompanying the drug contains statements which are 'false, misleading and contrary to fact.' The complaint also alleged that over ten million R.X.–120 tablets had been ordered by the defendants for distribution in interstate commerce.

"The proof on the Government's application for a preliminary injunction overwhelmingly established the Government's claims. The printed matter sent through the mails with the R.X.–120 tablets would lead readers to believe that without any special diet they could lose many pounds in a few days – '9 pounds in 10 days! * * * 18 pounds in 20 days! * * * 27 pounds in 30 days! * * * up to 49 pounds in 8 weeks!' The literature further claimed that the tablets had been released as safe by the United States Government; that until recently the drug could not be purchased without a doctor's prescription; that the drug is a new wonder drug and has received the most extensive clinical testing ever devoted to any drug; and that the drug depresses the appetite and decreases the desire for food. The affidavits of the Government's medical experts asserted that the drug does not possess significant appetite depressing properties. That the claims made by the defendants are false and exaggerated is the only conclusion which could be drawn from all the affidavits before the district court. From the record before the district court it was reasonable to conclude that there was every probability that the Government would prevail at the trial.

"The literature which accompanied the drug constituted a misbranding within the meaning of 21 U.S.C. §§ 321 and 352(a). As it also appeared that the defendants had limited resources and might well not be in a position to refund $14 to each purchaser, as promised if the drug did not accomplish the advertised weight loss, it cannot seriously be questioned that it was a proper exercise of discretion for the district court to enjoin the defendants prior to a plenary trial of the issues. *Joshua Meier Co. Inc.*, v. *Albany Novelty Manufacturing Co.*, 236 F. 2d 144 (2 Cir. 1956).

"The order is affirmed."

On 8–22–60, the defendants filed a notice of motion for discovery and inspection, which motion was granted by the court on 9–7–60, and, pursuant to which, various official samples, mailing wrappers, and sample records were shown to the defendants on 10–10–60.

On 12–20–60, a consent decree of permanent injunction was filed enjoining Wilson-Williams, Inc., and Jack Elliott, and each and all of their officers, agents, servants, employees, and representatives, and all and any persons in active concert or participation with them, and any corporation or firm in which the defendants and/or each of them is associated, directly or indirectly, or any

of them who receive actual notice of this decree by personal service or otherwise, from directly or indirectly doing any of the following acts with respect to *R.X.–120* or the same article by any other designation, or any similar article:

(a) Introducing into interstate commerce any such drug which, (i) is accompanied by the following written, printed, or graphic matter, or accompanied by any written, printed, or graphic matter, substantially to the same effect: Printed sheets headed "Released As Safe"; leaflets entitled "RX–120 FOR TREATMENT OF OVERWEIGHT AND OBESITY"; leaflets reading in part "Dear Friend: How would you like to close your eyes and suddenly find"; and order blanks to which are attached a guarantee reading in part "Keep This Guarantee * * * Free Trial"; (ii) bears or is accompanied by any written, printed, or graphic matter which states, represents, suggests, or implies that such article is capable of causing a person to lose 49 pounds in 8 weeks, 27 pounds in 30 days, 18 pounds in 20 days, 9 pounds in 10 days, and that such weight reduction is accomplished without special diet; that such article has been released as safe by the United States Government; that until recently such article could not be purchased without a doctor's prescription; that such article is a new wonder drug; that such article has received the most extensive clinical testing ever devoted to any drug; that such article depresses the appetite, decreases the desire for food by acting on the central nervous system, fights hunger contraction, and telegraphs a "stop signal" to the brain when one is tempted to overeat or indulge in between-meal snacks; and that such article is adequate and effective for the treatment of overweight or obesity; or which contains any other false or misleading representations or suggestions; or (iii) fails to state in its labeling, all of the diseases, conditions, symptoms, and purposes for which the article is intended to be used and for which it is represented, by any means, to the public;

(b) Doing or causing to be done, any act with respect to any such article of drug while such article is held for sale after shipment in interstate commerce, which act results in such article, (i) being accompanied by the written, printed, or graphic matter named above in subparagraph (a)(i), or by any written, printed, or graphic matter substantially to the same effect; (ii) bearing or being accompanied by any written, printed, or graphic matter containing the representations and suggestions described in subparagraph (a)(ii) above; or (iii) failing to state in its labeling, all of the diseases, conditions, symptoms, and purposes for which such article is intended to be used and for which it is represented, by any means, to the public.

7173. **Sea Brine.** (Inj. No. 402.)

COMPLAINT FOR INJUNCTION FILED: 6–23–61, S. Dist. Fla., against Florida Sea Brine Laboratories, Inc., Lakeland, Fla., and Henry Quednau, president, Eugene L. Durrance, general manager, and Ellsworth E. Durrance, vice president.

CHARGE: The complaint alleged that the defendants were engaged in the business of preparing, packing, selling, and distributing an article of drug designated as *Sea Brine*, in bottles which were labeled in part "SEA BRINE CONCENTRATED NATURAL SEA WATER CONTENTS This bottle contains 64 drams of highly concentrated 100 per cent pure Atlantic Ocean Water. Concentrated 10 times by vacuum evaporation. 64-DAY SUPPLY One teaspoon per day to be added to fruit, juice or vegetables or taken with regular tap water. The SALTY FLAVOR may be used as a seasoning in cooked foods. Dilute SEA BRINE with regular tap water (half and half) for mouthwash or gargle. CONCENTRATED AND BOTTLED BY FLORIDA SEA

BRINE LABORATORIES, INC. P.O. Drawer 2435 Lakeland, Florida"; that as a part of the distributional scheme to promote the sale of the drug the defendants caused the drug to be accompanied by certain labeling which consisted of reprints, in leaflet form, of newspaper articles which were entitled "Worry Clinic Sea Water Can Help Prevent Disease, by George W. Crane, Ph. D., M.D."; "You Are Invited to Write Dr. Crane * * * Worry Clinic"; "Chemical Smorgasbord vs. Cancer Dr. George W. Crane, Ph. D., M.D."; and "Worry Clinic Drink Sea Water, Crane Recommends, By George W. Crane, Ph. D., M.D.", and which contain recommendations for the use of sea water in the treatment and prevention of such serious diseases as cancer, diabetes, multiple sclerosis, leukemia, myasthenia gravis, Parkinson's disease, and arthritis; and to be accompanied by additional labeling which contained statements relating to the drug and consisted of posters entitled "Contains Natural Minerals and Chemicals * * * Sea Brine * * * Worry Clinic"; counter display cards entitled "Now Available * * * Sea Brine"; cardboard posters entitled "Worry Clinic Drink Sea Water, Crane Recommends"; and leaflets entitled "Sea Brine * * * From Ocean to You"; "Reprinted from the February 5, 1961 issue of the Lakeland Ledger Facts Indicated Ponce De Leon Was On Right Track"; "Bottling the Salty Sea"; and "Florida Sea Brine Laboratories, Inc. Sea Brine Analysis."

The complaint alleged further that the article was misbranded within the meaning of 502(a), in that the labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment and prevention of cancer, diabetes, multiple sclerosis, leukemia, myasthenia gravis, Parkinson's disease, arthritis, goiter, deficiency ailments, sterility, dental caries, ailments and infections of the eye, hangover, gray hair, and baldness; that the drug was a "chemical smorgasbord" for body glands, thereby providing for the proper function of the pancreas, liver, spleen, bone marrow, thyroid, and other organs to guard health and prevent sickness; and that the drug provided for rejuvenation, prolonged life and youth, and improved mental health; that the drug supplied significant amounts of all the essential minerals and trace minerals for special dietary and therapeutic purposes; that all of the trace minerals in the drug have been established as essential and important to good health; and that foods, as consumed, are lacking in all the minerals contained in the drug; and that the article was further misbranded within the meaning of 502(f)(1), in that the labeling failed to bear adequate directions for use because the directions for use with respect to the dosage, frequency, and duration of administration appearing on the labeling, were not adequate for the treatment and prevention of the diseases and conditions for which the drug was intended, since the drug was worthless for the treatment and prevention of such diseases and conditions, and adequate directions could not be given for the use of the drug in the treatment and prevention of such diseases and conditions.

DISPOSITION: On 6–27–61, a temporary restraining order was issued. On 7–5–61, the defendants having consented, a preliminary injunction was entered which enjoined the defendants from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and from delivering or causing to be delivered to persons in the State of Florida who are known to be engaged in doing interstate business, any product composed in whole or in part of ocean water or concentrated ocean water when labeled with any label which makes any reference to the use of the product in the treatment or prevention of disease, or which fails to set forth that the product is a seasoning for other

foods or beverages; but which permitted the defendants to sell the concentrated ocean water product in interstate commerce using a label which declared the product to be seasoning.

The injunction also enjoined the defendants against the introduction and delivery for introduction into interstate commerce, of any advertising or promotional materials containing reprints of articles by Dr. George W. Crane, or containing any statements recommending the use of the product *Sea Brine*, or any other product composed of ocean water or concentrated ocean water, in the prevention or treatment of diseases.

On 11–13–61, the defendants have consented, a decree was entered which caused the preliminary injunction, already entered, to become permanent.

7174. Capilon tablets. (F.D.C. No. 44220. S. No. 78–905 P.)

QUANTITY: 75,800 tablets, at Detroit, Mich., in possession of The Paul Plessner Co.

SHIPPED: Between 5–18–59 and 10–1–59, by Paul B. Elder Co., Bryan, Ohio.

LABEL IN PART: (Btl.) "Capilon Each tablet provides: Citrus Bioflavonoid Complex 100 mg. Rutin 100 mg. Ascorbic Acid 100 mg. * * * Sole Distributors The Paul Plessner Co. Detroit 16, Mich. * * * Caution: Federal law prohibits dispensing without a prescription."

ACCOMPANYING LABELING: Extra bottle labels and brochures entitled "Capilon Plessner."

RESULTS OF INVESTIGATION: The tablets were shipped to the dealer in bulk containers and were, during the normal course of the dealer's business operations, repacked into 100-, 500-, and 1,000-tablet bottles labeled as above.

The brochures were printed for the dealer and were used to promote the sale of the drug.

LIBELED: 2–8–60, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for relieving the symptoms of the common cold; preventing and controlling hemorrhage and respiratory conditions; protection against, and correction of, bleeding of threatened and habitual abortion, duodenal ulcers, uterine bleeding, and that bleeding associated with surgery; and 502(f)(1)—when shipped and while held for sale, the article failed to bear adequate directions for use for the purpose for which the article was intended, and it was not exempt from such requirement since it was not a drug required to be dispensed upon prescription.

DISPOSITION: 3–31–60. Consent—claimed by Paul Plessner Co. and relabeled.

7175. Multiglands injection. (F.D.C. No. 47294. S. No. 60–963 T.)

QUANTITY: 100 individually ctnd. 30-cc. vials at Detroit, Mich.

SHIPPED: 1–11–62, from Philadelphia, Pa., by Vitamix Corp.

LABEL IN PART: (Ctn. and vial) "30 CC. Multiple Dose Vial List No. 334 Multiglands (Plurigland Extract) Intramuscular Only * * * Caution: * * * Distributed By Len Tag & Company, Detroit 12, Mich."

LIBELED: On or about 4–17–62, E. Dist. Mich.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use and it was not entitled to any exemption from that requirement.

DISPOSITION: 7–6–62. Default—delivered to the Food and Drug Administration.

7176. **Amphetamine sulfate tablets.** (F.D.C. No. 47531. S. No. 11-328 T.)

QUANTITY: 15,000 tablets at Houston, Pa., in possession of David Ingram, M.D.

SHIPPED: Prior to 6-4-62, from outside the State of Pennsylvania.

RESULTS OF INVESTIGATION: Analysis indicated the article to be 10 milligram *amphetamine sulfate tablets.*

LIBELED: 6-6-62, W. Dist. Pa.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use and the article was not exempt from that requirement since it was a prescription drug which was not, or would not be, used or dispensed by the practitioner in the course of his professional practice, in accordance with the law.

DISPOSITION: 7-12-62. Default—destruction.

7177. **Vi-Testrin tablets.** (F.D.C. No. 47580. S. No. 56-947 T.)

QUANTITY: 315 100-tablet btls. at Houston, Tex., in possession of Savage Laboratories, Inc.

SHIPPED: 7-24-61, from St. Louis, Mo.

LABEL IN PART: (Btl.) "Vi-Testrin Vitamin-Hormone-Mineral Lipotropic Supplement * * * Manufactured for Savage Laboratories, Inc. Houston, Texas" and (btl. insert) "Vi-Testrin Tablets Each 3 tablets contain: * * * Folic Acid 0.4 mg."

RESULTS OF INVESTIGATION: The article was repacked into the bottles by the dealer from bulk drums shipped as described above. Examination showed that the article contained approximately 75 percent of the declared amount of folic acid.

LIBELED: 5-15-62, S. Dist. Tex.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported and represented to possess, in that it contained less folic acid than was declared on its label; 502(a)—the labeling contained false and misleading representations that the article was adequate and effective as a treatment for retarding the "aging process"; providing renewed vitality and feeling of well-being; aiding in forestalling the "aging process"; and preventing tissue deterioration; and 502(f)(1)—the labeling failed to bear adequate directions for use, and the article was not exempt from that requirement since it was a drug subject to the provisions of 503(b)(1)(B), and its labeling did not bear adequate information for use under which practitioners licensed by law to administer such drug could use the drug safely and for the purposes for which it was intended; and further, the labeling did not bear the name and quantity or proportion of each active ingredient of the drug.

DISPOSITION: 7-20-62. Default—destruction.

7178. **Merbels No. 2.** (F.D.C. No. 47678. S. No. 75-368 T.)

QUANTITY: 90 80-gram btls. and 11 100-gram btls. of *Merbels No. 2*, and 400 lbs. of sodium bicarbonate, 120 lbs. of magnesium carbonate, 350 lbs. of bismuth subgallate, and 125 lbs. of bismuth subcarbonate, in bulk drums, at Tracy, Calif., in possession of Merton Bell, t/a Bell Laboratories.

SHIPPED: Between 10-20-60 and 2-6-62, from Wyandotte, Mich., and St. Louis, Mo.

LABEL IN PART: (Btl.) "Merbels No. 2 * * * (Bell's Special Prescription) * * * Active Ingredients: Bismuth Subgallate, Bismuth Subcarbonate, Magnesium Carbonate, Sodium Bicarbonate, etc. * * * Manufactured by Bell Labora-

tories * * * Tracy, Calif."; (drum) "Bicarbonate of Soda U.S.P. Powdered," "Magnesium Carbonate USP Powder," "Bismuth Subgallate N.F. (Powder)," and "Bismuth Subcarbonate U.S.P. (Powder)."

ACCOMPANYING LABELING: Leaflets entitled "Merbels Special Prescription Safe and Sure For Chronic Sick, Gassy, Nervous Stomachs" and "Why Suffer With Your Stomach?"

RESULTS OF INVESTIGATION: The article in the bottles was manufactured by the dealer from the bulk raw materials mentioned above.

LIBELED: 6–21–62, N. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate, safe, and effective treatment for stomach distress due to ulcers; chronic sick, gassy, ulcerous stomachs; more serious stomach ailments; dizziness; peptic ulcers; colitis; and all ailments connected with stomach trouble, except cancer; and 502(f)(1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 7–9–62. Consent—claimed by Merton Bell and released under bond for relabeling.

7179. **Nutri-Plex food supplements.** (F.D.C. No. 47420. S. Nos. 158/9 T, 163/4 T.)

QUANTITY: 40 pkgs., 62 unlabeled packets each, of *Nutri-Plex "E"*; 10 pkgs., 62 unlabeled packets each, of *Nutri-Plex C–1*; 1 pkg. of *Nutri-Plex "A"*; and 43 pkgs., 3 ctns. each, of *Nutri-Plex "F"*, at Sarasota, Fla., in possession of Nutri-Foods & Products Co.

SHIPPED: Between 1–16–62 and 3–1–62, from Glendale, Calif.

LABEL IN PART: (Pkg.) "Nutri-Plex 'E' Each packet contains 100 I.U. Vitamin E * * * and 1 milligrams vitamin B_1 * * * Distributed by Nutri-Foods & Products Co., Sarasota, Fla.," "Nutri-Plex C–1 Concentrated Chlorophyll Beverage * * * Contents 62 packets * * * Nutri-Foods & Products Co.," "Nutri-Plex 'A' Food Supplement * * * Contains 60 Yellow Tablets and 180 Gray Mineral Tablets * * * Dist. by Nutri-Foods and Products Co.," and "Nutri-Plex 'F' Food Supplement * * * Contains 180 White Vitamin Tablets and 360 Gray Mineral Tablets * * * Distributed by Nutri-Foods and Products Co."

ACCOMPANYING LABELING: Leaflets entitled "Vitamins and Minerals—Dr. Jonas E. Miller," which were prepared on order of the dealer.

LIBELED: 3–28–62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of heart conditions, "thrombitis," bleeding, nervous disorders, poor digestion, skin troubles, mental aberrations, anemia, cretinism, and unregulated cholesterol and fatty deposits in blood vessels; and 502(f)(1)—the labeling failed to bear adequate directions for use of the articles in the treatment and prevention of heart conditions, premature death, improper growth, cancer, poor teeth, flu, and other conditions due to bacteria, viruses, and germs; arthritis, rheumatism, aches and pains, gland trouble, nosebleed, hardening of the arteries, stomach ulcers, insomnia, and strokes; which were the conditions, diseases, and purposes for which the articles were intended, and for which they were prescribed, recommended, and suggested in oral statements made by Mr. Jonas E. Miller (owner of Nutri-Foods Products Co.).

DISPOSITION: 7–6–62. Default—destruction.

7180. **Nutri-Bio food supplement.** (F.D.C. No. 47563. S. Nos. 19–378/9 T.)

QUANTITY: 60 units in ctns. and cans at Grand Prairie, Tex., in possession of Warren S. King.

SHIPPED: 1–19–62 and 3–21–62, from Beverly Hills, Calif.

LABEL IN PART: (Ctn.) "VITAMINS AND MINERALS from natural food sources * * * 720 Mineral Tablets 364 Vitamin Tablets * * * Formulated for and Distributed by NUTRI-BIO"; (can) "Protein Ready to Use Instant Mix Vanilla Flavor * * * Formulated for and Distributed by NUTRI-BIO"; and (ctn. and can) "NUTRI-BIO dietary food supplement * * * Formulated for and Distributed by NUTRI-BIO CORPORATION, Beverly Hills, California * * * Available only through Authorized Nutri-Bio Distributors."

LIBELED: On or about 5–4–62, N. Dist. Tex.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment and prevention of asthma, heart conditions, overweight and underweight conditions, enlarged heart, sore throat, colds, baldness, fatigue, to build up resistance to all kinds of diseases, and to prevent the loss of teeth; which were the conditions and purposes for which the articles were intended, and for which they were prescribed, recommended, and suggested in oral statements made by Warren S. King, Nutri-Bio sales agent.

DISPOSITION: 6–19–62. Default—destruction.

7181. **Hexol germicide.** (F.D.C. No. 47390. S. Nos. 29–492/5 T.)

QUANTITY: 39 6-oz. btls., 20 12-oz. btls., 27 24-oz. btls., and 72 2-oz. btls., at Kansas City, Mo.

SHIPPED: Prior to and on or about 8–23–61 and 1–22–62, from Colorado Springs, Colo., by Hexol, Inc.

LABEL IN PART: (Btl.) "Hexol * * * Germicide for Bathroom Feminine Hygiene Baby Care Disinfects-Deodorizes * * * Active Ingredients: Alpha, Beta Terpineol and Related Terpene Derivatives; Soap * * * Hexol, Inc., San Francisco, Calif."

LIBELED: 3–16–62, W. Dist. Mo.

CHARGE: 502(f)(2)—when shipped, the article was offered as an antiseptic for first aid use, and its labeling failed to bear a statement warning that in case of deep or puncture wounds, or serious burns, or if redness, irritation, swelling, or pain persisted or increased, or if infection occurred, that use of the article should be discontinued and a physician consulted; and in that it was offered as a douche and its labeling failed to bear a statement warning that the article should not be used more often than twice a week unless directed by a physician.

DISPOSITION: 7–23–62. Default—destruction.

7182. **Harmonizer device.** (F.D.C. No. 46715. S. No. 42–508 P.)

INFORMATION FILED: 7–6–62, S. Dist. Calif., against Catherine E. Harmon, t/a Sound Control Development Co., Alhambra, Calif.

SHIPPED: 9–30–59, from California to Washington.

LABEL IN PART: (On device) "Harmonizer" and "Sound Control Development Co. Mach 09 117 Volt AC 60 Cyl California."

ACCOMPANYING LABELING: Leaflets entitled "Harmonizer Instruction Chart," "Don't Give Up—Wake Up!," and "Sound Control Development Co. Presents. . . . The 'Harmonizer'."

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the device was an adequate and effective treatment for arthritis, asthma, sinus trouble, migraine, bursitis, sciatica, neuritis, goiter, epilepsy, prostate trouble, high blood pressure, heart disease, kidney disease, glandular and nerve degeneration, ulcers, cysts, anemia, colitis, osteomyelitis, varicose veins, skin diseases, chronic infections, bronchitis, tumors, and Parkinson's disease; that the device was the "Only Dual unit Sound Therapy for treatment of disease; composed of Audible (low frequency) and Ultra-Sound controlled vibration"; that the device was specific for nerve regeneration; increased circulation, tissue repair, gland and muscle stimulation; that the device was unsurpassed for control of inflammation, elimination of infection, decalcification, tumor disintegration, and pain relief; that the application of pads of the device to the sinuses, thyroid, anterior and posterior cervicals, mastoid, parotid, submaxillary areas, chest, dorsals, hands, feet, shoulders, elbows, wrists, ankles, knees, arms, legs, viscera, lumbars, sacrum, and hips would have therapeutic value in the treatment of disease conditions in those areas; and the labeling also was misleading because it failed to reveal the material fact that the device, when used as directed, produced only radio-frequency waves and contained nothing capable of converting such waves to audible sound or ultrasound waves; and 502(f)(1)—the labeling failed to bear adequate directions for use, and it was not feasible to write adequate directions for use since the article was worthless for any medical purpose.

PLEA: Nolo contendere.

DISPOSITION: 9–17–62. $500 fine.

7183. Neurolinometer, Radioclast, Electron-O-Ray, and Quto-Electronic Instrument devices. (Inj. No. 423.)

COMPLAINT FOR INJUNCTION FILED: 3–23–62, N. Dist. Ohio, against Electronic Instrument, Inc., Tiffin, Ohio, Dale C. Mowery, president, and Helen R. Mowery, secretary-treasurer.

NATURE OF BUSINESS: The complaint charged that the defendants were in the business of manufacturing, assembling, repairing, selling, and distributing in interstate commerce, devices designated as *Neurolinometer*, *Radioclast Model 40*, *Radioclast Model P*, *Radioclast Treating Unit*, *Electron-O-Ray Model 46*, *Electron-O-Ray Model 51*, and *Quto-Electronic Instrument Model 0–20–1 P*. The devices were accompanied by labeling consisting of leaflets entitled "Electronic Laboratory Analysis Rates: Numerically Arranged" and "Electronic Analysis"; and pamphlets entitled "Manual Electron-O-Ray Model 500."

The complaint alleged that the *Neurolinometer* was an electronic device replete with dials, switches, and lights, contained in a case similar to a small traveling bag. In use, a metal disk attached to a handle was passed up and down over the spine. The disk was supposed to detect "bad spots" or nerve impingements along the spine, alleged to be indicative of disease conditions elsewhere in the body. Minute nerve impulses were supposed to be transmitted thru the disk to a bakelite detecting plate in the *Neurolinometer*. The operator of the device was directed to rub his fingers over the plate and detect a "stickiness" at the time the disk is passing over any bad spot in the spine. The trouble spots were then treated by chiropractic adjustments to relieve the alleged nerve impingement at that spot.

The complaint alleged also that the *Radioclast Model 40* device consisted of a desk-type console which contained a large control panel with 24 control knobs, 2 meters, a timer, 6 pilot lights, a push button designated as "food test" and 9 electroterminal jacks. Included at the bottom of the control panel was a metal detector plate, a metal cup, and a glass or bakelite detector plate. The various knobs and dials were used to measure, select, and control the frequencies and intensities. The "food test" portion of the device was alleged to be of use to the operator in selecting an appropriate diet for the patient. When plugged into an electrical outlet, the treatment portion of the device was intended to supply to the patient various electrical frequencies generated by the device. The diagnostic portion of the device purportedly measured various electrical frequencies supposedly emanating from the patient, and, depending upon the readings secured, it was claimed that the presence or absence of diseases or abnormal body conditions may be determined.

This device was intended to detect, identify, and measure various hypothetical frequencies emanating from all the cells in the body, normal cells, diseased cells, or pathogenic organisms. In this manner, a diagnosis of the disease-body was allegedly obtained as to the organs involved, pathogenic organism involved, and the intensity of the disease. The patient was then "treated" by passing certain harmonizing or tuned frequencies, determined by the diagnostic or analysis section of the device, back into the body. The basic elements of the electronic circuit by which the above was accomplished, were two tuned amplifiers to measure input and a radio-frequency oscillator to furnish the treatment output.

The claimed analysis or diagnosis was made by the device amplifying the detected frequencies and applying them to a wire screen under the bakelite detector plate. The operator manipulated the dials with one hand and would rub the bakelite plate with the fingers of the other hand. Supposedly, when the device was in resonance with a frequency from the body, the operator's fingers became "sticky" on the bakelite plate. In actual use, this device was not capable of detecting or measuring any characteristic frequencies from the body since such frequencies were nonexistent.

For the purpose of selecting an appropriate diet for a patient, a "food test plate" was provided connected to the "in" terminal. Since no electrical ground return was associated with the "food test plate," only random capacitative pickup could be associated with this terminal. The device was intended to measure frequencies characteristic of the foods placed on the test plate.

The complaint alleged also that the *Radioclast Model P* device was similar in construction to the aforesaid *Radioclast Model 40* device, excepting that it was smaller and portable. The panel of this smaller device contained 11 control knobs, two switches, electrode connections, and a similar glass or bakelite detector plate. This smaller unit was intended for the same general purposes as the aforesaid *Radioclast Model 40* device, and in use was sometimes carried into the homes of patients, for their convenience.

In actual use, the patient would hold a bipolar electrode in one hand and the operator would place a small metal loop, or pointer electrode, on the various areas of the patient's body, supposedly detecting and measuring the hypothetical frequencies characteristic of specific disease conditions in the body. Two metal electrodes were placed over the area to be treated and a high-frequency current in harmony with the measured frequency was returned to the body.

The complaint alleged also that the *Radioclast Treating Unit* was a device with a panel containing 6 control knobs, one meter, and four electrode connections. Two sets of electrodes are supplied for use with this device, namely,

(a) 2 electronic electrodes which furnished a low-voltage, low-frequency current to the body; and (b) 2 magnetic electrodes which set up a magnetic field in the portion of the body between the electrodes. The bottom of the unit was a storage drawer.

In the actual operation of the *Radioclast Treating Unit*, the two electronic electrodes were placed over the liver and spleen or at the base of the neck and the magnetic electrodes were placed on each side of the diseased portion of the body. The electronic electrodes applied a 7.2-cycles-per-second electrical current to the body, but this current was of no known therapeutic value as applied by this device. The magnetic electrodes produced a weak varying magnetic field of no known therapeutic value, when applied to a patient.

The complaint alleged also that the *Electron-O-Ray Model 46* device was a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. The electronic components within the case were a power supply, an oscillator, and an amplifier. In the operation of the device, the patient would hold an input electrode in one hand and the operator would place a loop, or pointer electrode, on the body over the viscera to be checked. The "Visceral" dials (marked "VISC") were used to determine the organ involved or the location of the existing disease condition. The "Vibratory Rate" dials (marked Vr) were set to the disease or pathogen being checked. The "measure" dials were purportedly used to determine the amount or intensity of the disease conditions found according to the "Vr" and "VISC" dials. The only reaction indicator for the device was an alleged feeling of "stickiness" experienced by the operator on rubbing his fingers on the bakelite detector plate. By this same procedure, with the use of a "food test plate," a diet purportedly may be selected for a patient.

The complaint alleged also that the *Electron-O-Ray Model 51* device was a smaller portable model of the aforesaid *Electron-O-Ray Model 46* device. Contained in a carrying case about 16″ x 16″ x 8″ in size, the device contained a control panel bearing 2 rows of five and six dials on the panel. The Model 51 device was equipped with electrode plates for application to the body of the patient being diagnosed or treated, in the same manner as the ones supplied with the larger *Electron-O-Ray Model 46* device.

The complaint alleged also that the *Quto-Electronic Instrument Model 0–20–1 P* was a device contained in a suitcase-type carrying case, which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. Electronic components within the case formed a power supply, oscillator, and amplifier for the detection and amplification of high-frequency electrical waves given off by the body. The device was intended to be able to measure the intensity of a disease in the body, the pathogen or cause of the disease, and the organ or location of the disease in the body.

CHARGE: The complaint charged that when the *Neurolinometer*, in a new, used, or repaired condition was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(f)(1), in that its labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis of disease in man, in that said device was worthless for use for such purpose, and adequate directions cannot be given for the use of said device for such purpose.

The complaint charged also that when the *Radioclast devices*, in a new, used, or repaired condition, were caused to be introduced and delivered for introduction into interstate commerce, the devices were misbranded within the meaning of 502(a), in that their labeling, namely, leaflets designated "Elec-

tronic Laboratory Analysis Rates: Numerically Arranged" and "Electronic Analysis," accompanying said device, contained statements which represented and suggested that said devices were capable of diagnosing and treating disease conditions of the brain, tonsils, prostate, spinal cord, trachea, lungs, kidneys, stomach, heart, liver, bones, eyes, and numerous other disease conditions, which statements were false and misleading since said devices were not capable of diagnosing and treating any disease conditions; and the devices were misbranded within the meaning of 502(f)(1), in that the labeling of said devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for the diagnosis and treatment of disease in man and for the use of said *Radioclast Model 40* as a food tester and diet selector, in that said devices were worthless for use for such purposes, and adequate directions cannot be given for the use of said devices for such purposes.

The complaint charged also that when the *Electron-O-Ray Model 46* device, in a new, used, or repaired condition, was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(a), in that its labeling, namely, pamphlets entitled "Manual Electron-O-Ray Model 500," accompanying said device, contained statements which represented and suggested that said device was capable of diagnosing and treating disease conditions of the uterine cervix, appendix, thyroid, testes, ovaries, mammary glands, lungs, kidneys, stomach, heart, liver, ears, eyes, teeth, brain, blood, and other disease conditions of the organs of the body, which statements were false and misleading since said device was not capable of diagnosing and treating such disease conditions and was worthless for any medical purpose: and the device was misbranded within the meaning of 502(f)(1), in that the labeling of said device failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man and for use as a food tester and diet selector, in that said device was worthless for use for such purposes, and adequate directions cannot be given for the use of said device for such purposes.

The complaint charged also that when the *Electron-O-Ray Model 51*, in a new, used, or repaired condition, was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(f)(1), in that its labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man, in that said device was worthless for use for such purposes, and adequate directions cannot be given for the use of said device for such purposes.

The complaint charged also that when the *Quto-Electronic Instrument Model 0–20–1 P.* in a new, used, or repaired condition, was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(f)(1), in that its labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man, in that said device was worthless for use for such purposes, and adequate directions cannot be given for the use of said device for such purposes.

The complaint alleged also that the defendants had been warned on several occasions that the devices were worthless, by various seizure actions between 1958 and 1961.

DISPOSITION: 4–18–62. The defendants consented to the entry of a decree but denied the allegations. The decree which was entered perpetually enjoined the defendants, their officers, agents, servants, employees, representatives, and

all and any persons in active concert or participation with them from directly or indirectly introducing or causing to be introduced and delivering or caused to be delivered for introduction into interstate commerce, and more particularly, from delivering or causing to be delivered to customers and other persons living outside the State of Ohio for transportation in interstate commerce, the devices, whether new, used, or repaired, designated as *Neurolinometer, Radioclast Model 40, Radioclast Model P, Radioclast Treating Unit, Electron-O-Ray Model 46, Electron-O-Ray Model 51,* and *Quto-Electronic Instrument Model 0–20–1 P,* including their components, parts, and accessories, the same devices by any other designation, and any similar devices.

7184. Neurolinometer device and Research Model device. (F.D.C. No. 47689. S. Nos. 50–154/5 T.)

QUANTITY: 2 devices at Woodland, Calif.

SHIPPED: Between 6–20–58 and 6–30–60, from Cumberland, Wis., by the Foundation For The Advancement of Chiropractic Research, Inc., and the Toftness Chiropractic Clinic.

LABEL IN PART: (On device) "Neurolinometer Toftness System, Cumberland, Wisconsin" and "Research Model * * * This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purposes. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic."

ACCOMPANYING LABELING: Book entitled "In Sickness and In Health – a publication of The Foundation For The Advancement of Chiropractic Research, Inc., copyright 1958, First Edition"; reprint entitled "The Journal Reports on The Neurolinometer"; and booklet entitled "Researching The Chiropractic Adjustment by I. N. Toftness, D.C., Ph. C. copyright 1951."

RESULTS OF INVESTIGATION: Investigation indicated that the *Neurolinometer* was a device housed in a black, suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

The device was in the possession of David A. Tuscher, D.C., and was used by him as a diagnostic tool or adjunct in connection with other diagnostic procedures to determine the location of subluxations or points of nerve interference along the spine.

Investigation indicated that the *Research Model* was a device housed in a grey-colored box, one end of which was a storage well containing a white powder used to dry the surface of the bakelite detector plate in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support. The device was intended to be used by placing the probe in contact with the supposedly affected part of the spine. Meanwhile, the operator rubbed his fingers across a metal plate attached to the device until a "pull" was felt on the fingers, while a numbered dial on the control panel was turned with the operator's other hand.

The device was in the possession of a doctor of chiropractic other than David A. Tuscher.

CHARGE: *Neurolinometer device*, 502(a)—while held for sale, the book entitled "In Sickness and in Health" accompanying the device, contained false and misleading representations that the article was adequate and effective as a diagnostic device in measuring nerve interference; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions cannot be given for the use of the article for such purpose.

Research Model device, 502(a)—when shipped, the label statements "Research Model" and "This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purposes. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic," were false and misleading, as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; 502(b)(1)—the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purposes, and adequate directions cannot be given for the use of the article for such purpose.

DISPOSITION: 9–20–62. Default—delivered to the Food and Drug Administration.

7185. Neurolinometer device. (F.D.C. No. 47707. S. No. 17–796 T.)

QUANTITY: 1 device at Fulton, Ky., in possession of Virgil H. Barker, D.C.

SHIPPED: Between 1–1–54 and 12–30–55, from Cumberland, Wis., by Toftness Chiropractic Clinic.

LABEL IN PART: (Original label) "Neurolinometer Toftness System Cumberland, Wis."; (added sticker label) "This instrument has no known treating, diagnostic or analytical value."

ACCOMPANYING LABELING: Book entitled "In Sickness and in Health, a publication of the Foundation for the Advancement of Chiropractic Research, Inc. Offices at Cumberland, Wisconsin, Copyright 1957."

RESULTS OF INVESTIGATION: Examination indicated that the device was housed in a black, suitcase-type container about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

The sticker label had been placed on the face of the device by the dealer, who had had the accompanying labeling displayed on a table with the device.

LIBELED: 7–25–62, W. Dist. Ky.

CHARGE: 502(a)—when shipped and while held for sale, the label statement "This instrument has no known treating, diagnostic or analytical value," was false and misleading, as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; 502(a)—statements in the accompanying labeling represented and suggested that the article was of value in the diagnosis of disease in man, which statements were false and misleading, since the article was worthless for such purposes; and 502(f)(1)—the labeling failed to bear adequate directions for the use for the purposes for which it was intended, namely,

for the diagnosis of disease in man, in that the article was worthless for use for such purposes, and adequate directions could not be given for the use of the article for such purposes.

DISPOSITION: 9–11–62. Default—delivered to the Food and Drug Administration.

7186. Neurolinometer device (2 seizure actions). (F.D.C. Nos. 47711, 47712. S. Nos. 60–649 T; 18–135 T.)

QUANTITY: 2 devices, at Ironwood, Mich., and Conroe, Tex.

SHIPPED: Between 8–1–54 and 7–31–56, from Cumberland, Wis., by Emil Kuitunen, D.C., and Walter E. Moore.

LABEL IN PART: "Neurolinometer Toftness System Cumberland, Wisconsin."

LIBELED: 7–10–62, W. Dist. Mich.; 7–11–62, S. Dist. Tex.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 8–14–62; 10–5–62. Default—one device destroyed and one device delivered to the Food and Drug Administration.

7187. Radioclast device and Electronic Analysis Instrument. (F.D.C. No. 46558. S. Nos. 16–401/2 T.)

QUANTITY: 2 devices at Owensboro, Ky.

SHIPPED: 6–1–61 and 7–28–61, from Tiffin, Ohio, by L. L. Roby Manufacturing Corp.

LABEL IN PART: "Auto Electronic Radioclast Model 20 Series 800 Electronic Instrument Co. Tiffin, Ohio * * * Reconditioned" and "Electronic Analysis Instrument Model F * * * Manufactured by L. L. Roby Manufacturing Corp. Tiffin, Ohio."

RESULTS OF INVESTIGATION: The *Radioclast device* had been previously shipped by the dealer to the shipper for repairs. Examination indicated that the *Radioclast* was a wooden cabinet containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of 3 dials intended for use in determining the identity of diseased organs. Three other dials purported to identify the disease conditions present, and additional dials purported to determine the identity of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to locate the point of maximum reaction and thus determine the location of the disease in the body.

The *Electronic Analysis Instrument* was a wooden console cabinet fitted with a control panel containing a direct current milliammeter, two pilot lights, switches, and 12 dials. The device did not generate an electric current but purported to measure electrical impulses allegedly emanating from disease tissue. The device had a detector plate as an attachment, used to diagnose the location and extent of disease.

LIBELED: 10–9–61, W. Dist. Ky.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling failed to bear adequate directions for use.

DISPOSITION: On or about 12–14–61, Wayne E. Gore, D.C., Owensboro, Ky., claimed the articles and denied that they were misbranded. On 6–8–62, the

Government served written interrogatories on the claimant. On 8–7–62, the Government filed a motion to strike the pleading of the claimant from the record since more than 15 days had elapsed since service of the Government's interrogatories, and no answer to them had been filed.

On 8–15–62, the court ordered the claim and answer of Wayne E. Gore, D.C., stricken from the records of the case. On 9–4–62, all persons having, or claiming, an interest in the devices being in default, the devices were condemned and were thereafter released to the Food and Drug Administration.

7188. Micro-Dynameter devices and accessories. (F.D.C. No. 47928. S. Nos. 86–783/4 T.)

QUANTITY: 2 devices and 1 ctn. of accessories at Chicago, Ill.

SHIPPED: 6–25–62 and 6–28–62, from Atlanta, Ga., and Red Bank, N.J. These were return shipments.

LABEL IN PART: (Control panel) "Manufactured by Ellis Research Laboratories, Inc., Chicago * * * The Ellis Micro-Dynameter" and (metal plate) "For Scientific Body Analysis The Ellis Micro-Dynameter."

ACCOMPANYING LABELING: Literature entitled: "Bulletin T–4, A Practical Manual for Micro Dynameter Model SA–2," "An Introduction to Vivo-Tone," and "Vivo Tone Formulae"; bulletins Release #1 through #8; letter dated 7–19–61, signed by R. W. Ellis; and a black, looseleaf notebook containing approximately 22 various pieces of literature pertaining to the *Micro-Dynameter device.*

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8–1–62, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f)(1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 9–10–62; amended decree 9–11–62. Default—delivery to the Food and Drug Administration.

7189. Micro-Dynameter devices with accessories (4 seizure actions). (F.D.C. Nos. 47938, 47948/9, 47958. S. Nos. 19–622 T; 71–401 T; 16–261/3 T, 16–265 T; 72–429 T; 16–264 T; 77–344/5 T.)

QUANTITY: 10 devices with various accessories, at Daingerfield and Nederland, Tex.; Cincinnati and Hillsboro, Ohio; Dayton, Ohio; and Cartersville and Summerville, Ga.

SHIPPED: Between 1–1–46 and 10–31–60, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: (Metal plate on device cabinet) "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago, U.S.A."

ACCOMPANYING LABELING: (Some devices) Booklets entitled "The History of Cranial Reflex" and "Bulletin T–4, A Practical Manual for Micro-Dynameter Model SA–2"; black looseleaf notebook; or various leaflets, folders, brochures, bulletins, instruction manuals, and descriptive literature, pertaining to the *Micro-Dynameter*.

LIBELED: 8–11–62 and 8–10–62, E. Dist. Tex.; 8–14–62 and 9–19–62, S. Dist. Ohio; 8–24–62, S. Dist. Ohio; 8–10–62, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing diseases; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemptions from that requirement.

DISPOSITION: 9–19–62; 9–17–62; 10–12–62; 10–9–62; 9–14–62. Default—7 devices destroyed; 3 delivered to the Food and Drug Administration.

7190. Micro-Dynameter device with attachments and manuals. (F.D.C. No. 47926. S. No. 7–977 T.)

QUANTITY: 1 device at Providence, R.I.

SHIPPED: Prior to 7–10–62, from Chicago, Ill.

LABEL IN PART: (Metal plate on device cabinet) "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

LIBELED: 8–15–62, Dist. R.I.

CHARGE: 502(a)—when shipped or while held for sale, the labeling of the device, namely, the device label and the manuals pertaining to use of the device, accompanying the device, contained false and misleading representation that the article was adequate and effective for diagnosing diseases; and 502(f)(1)—its labeling failed to bear adequate directions for use, and it was not exempt from that requirement.

DISPOSITION: 8–16–62. Default—destruction.

7191. Micro-Dynameter device. (F.D.C. No. 47962. S. No. 69–155 T.)

QUANTITY: 1 device at Chicago, Ill.

SHIPPED: 7–9–62. from Lake Worth, Fla.

LABEL IN PART: (Metal plate on device cabinet) "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago, U.S.A."

ACCOMPANYING LABELING: Literature pertaining to the device.

RESULTS OF INVESTIGATION: This was a return shipment, consigned to the manufacturer.

Examination indicated that the device was essentially a galvanometer for measuring electrical currents and electrical potentials of small magnitude. It was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter, was generated by closing the circuit between

two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8–10–62, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the device contained false and misleading representations that the article was adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 9–11–62. Default—delivered to the Food and Drug Adminstration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

7192. Imitation Hydrodiuril tablets. (F.D.C. No. 45561. S. Nos. 12–455 R, 13–686 R.)

INFORMATION FILED: 3–17–61, N. Dist. Ill., against Americo R. Scala, Chicago, Ill., and Jules G. H. Gertz, Chicago, Ill.

ALLEGED VIOLATIONS: On 5–1–60, while a number of *imitation Hydrodiuril tablets* were being held for sale, Americo R. Scala caused the drug to be offered for sale and sold as Hydrodiuril tablets, which act resulted in the tablets being misbranded.

On 7–6–60, while a number of *imitation Hydrodiuril tablets* were being held for sale after shipment in interstate commerce, Jules G. H. Gertz caused the drug to be offered for sale and sold as Hydrodiuril tablets, which act resulted in the tablets being adulterated.

On 7–6–60, while a number of *imitation Hydrodiuril tablets* were being held for sale after shipment in interstate commerce, the defendants caused the drug to be offered for sale and sold as Hydrodiuril tablets, which act resulted in the tablets being misbranded.

CHARGE: 501(d)(2)—tablets other than Hydrodiuril tablets had been substituted for Hydrodiuril tablets; 502(i)(2)—the article was an imitation of another drug, Hydrodiuril; and 502(i)(3—the article was offered for sale under the name of another drug, namely, Hydrodiuril.

PLEA: Guilty.

DISPOSITION: 5–17–61; 6–15–61. Each defendant fined $500, plus costs.

7193. Imitation Serpasil tablets and imitation Equanil tablets. (F.D.C. No. 46650. S. Nos. 1–857 R, 45–924 R, 58–093/4 R.)

INFORMATION FILED: 10–24–61, M. Dist. Ga., against Crow's Drug Store, Inc., t/a Crow's Drug Store, Inc., C&D Pharmacy, and Carswell & Dooley Prescription Pharmacy, Athens, Ga.; Henry J. Carswell, Jr., president; and Grant L. Dooley, vice president.

ALLEGED VIOLATIONS: Between 1–14–58 and 4–5–61, while quantities of *imitation Serpasil tablets* and *imitation Equanil tablets* were being held for sale after shipment in interstate commerce, the defendants caused the drugs to be offered for sale and sold, and also caused *imitation Serpasil tablets* to be re-

*See also Nos. 7166, 7177.

packed into bottles bearing the Serpasil labels, which acts resulted in the drugs being misbranded.

CHARGE: *Imitation Serpasil tablets*, 501(d)(2)—the article had been substituted for Serpasil tablets; 502(a)—the label statements "Serpasil 0.25 mgm" and "Tablets 0.25 mg. SERPASIL" appearing on the repacked bottles were false and misleading in that the statements represented that the drug consisted of Serpasil tablets, whereas, the drug consisted of *imitation Serpasil tablets;* 502(i)(2)—the article was an imitation of another drug, Serpasil; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Serpasil.

Imitation Equanil tablets, 501(d)(2)—the article had been substituted for Equanil tablets; 502(i)(2)—the article was an imitation of another drug, Equanil; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Equanil.

PLEA: Nolo contendere.

DISPOSITION: 12–5–61. Corporation—$600 fine; each individual—$600 fine.

7194. **Soda mint tablets.** (F.D.C. No. 47535. S. No. 30–437 T.)

QUANTITY: 9 10,000-tablet ctns. at Camarillo, Calif.

SHIPPED: 9–19–61, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Ctn.) "Robinson 10,000 Tablets No. 589 Soda Mint 5 Grain Contains Soda Bicarbonate and Oil Of Peppermint Dose * * * Distributed by Robinson Laboratory, Inc. San Francisco, California."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and repacked by the dealer in cartons described above.

LIBELED: 6–7–62, S. Dist. Calif.

CHARGE: 501(d)(2)—when shipped, diethylstilbestrol had been substituted in part for sodium bicarbonate.

DISPOSITION: 7–2–62. Default—destruction.

7195. **Barestrogen tablets.** (F.D.C. No. 43339. S. No. 59–293 P.)

QUANTITY: 1 1,000-tablet btl. and 8 500-tablet btls. at Baltimore, Md.

SHIPPED: 7–7–58, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: "Barestrogen 1.25 Mg. Each Tablet Contains: Naturally occurring water soluble Conjugated Estrogens equivalent in biological activity to 1.25 mg. of Sodium Estrone Sulfate. * * * distributed by the Barre Drug Company, Baltimore, Md."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 45 percent of the labeled amount of water-soluble conjugated estrogens calculated as sodium estrone sulfate.

LIBELED: 8–7–59, Dist. Md.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each Tablet Contains: * * * water soluble Conjugated Estrogens equivalent in biological activity to 1.25 mg. of Sodium Estrone Sulfate" was false and misleading.

DISPOSITION: 9–17–59. Default—destruction.

7196. Conjugated estrogen tablets. (F.D.C. No. 47537. S. No. 37–234 T.)

QUANTITY: 13,900 tablets at Birmingham, Ala., in possession of Veltex, Inc.

SHIPPED: 12–20–57, from St. Louis, Mo.

LABEL IN PART: "VELESTRON CONJUGATED ESTROGENS 1.25 MG. THE VELTEX COMPANY, DISTRIBUTORS, BIRMINGHAM, ALABAMA."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and repacked by the dealer into containers with labels as described above.

Analysis showed that the article contained materially less than the declared amount of conjugated estrogens.

LIBELED: 6–6–62, N. Dist. Ala.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Conjugated Estrogens 1.25 MG" was false and misleading as applied to a product containing less than the declared amount of conjugated estrogens.

DISPOSITION: 7–6–62. Default—destruction.

7197. Rubber prophylactics. (F.D.C. No. 47528. S. Nos. 29–805/6 T.)

QUANTITY: 70 gross ctns. (dry), and 55 gross ctns. (wet), each containing 6 plastic containers of 24 individually foil-wrapped prophylactics, at Omaha, Nebr.

SHIPPED: 4–11–62, from North Kansas City, Mo., by Dean Rubber Co.

LABEL IN PART: (Ctn.) "Peacocks Dry Rubber [or "Peacocks Redi-Wet"] in foil, Dean Rubber Mfg. Co. North Kansas City-Missouri."

RESULTS OF INVESTIGATION: Examination showed that 1.2 percent of the dry prophylactics examined and 1.7 percent of the wet prophylactics examined were defective in that they contained holes.

LIBELED: 6–4–62, Dist. Nebr.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they were purported to possess.

DISPOSITION: 6–8–62. Consent—claimed by Dean Rubber Manufacturing Co. and destroyed.

7198. Rubber prophylactics. (F.D.C. No. 47516. S. No. 11–834 T.)

QUANTITY: 27 gross ctns., each containing 48 3-unit boxes, at Kenmore, N.Y.

SHIPPED: 4–16–62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Ctn. and box) "Peacocks * * * Redi-Wet Rubbers in Foil * * * No. 10 Dean Rubber Mfg. Co. North Kansas City, Mo." and (box) "3 Peacocks * * * An Aid In Preventing Venereal Diseases."

RESULTS OF INVESTIGATION: Examination showed that 1.04 percent of the article was defective in that it contained holes.

LIBELED: 5–31–62, W. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Diseases" was false and misleading as applied to a product containing holes.

DISPOSITION: 6–28–62. Consent—claimed by Dean Rubber Manufacturing Co. and ordered released under bond for testing or destruction.

7199. **Rubber prophylactics.** (F.D.C. No. 47509. S. No. 24–572 T.)

QUANTITY: 446 gross ctns., 12 boxes each, containing 4 pkgs. of 3 prophylactics each, at Cleveland, Ohio.

SHIPPED: 3–14–62, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Ctn.) "Sold For The Prevention of Disease Only One Gross No. 60 48 boxes of 3's"; (box) "Tip Tex Quality Supreme * * * Packed by Schaeffer Products Co., Inc. Cleveland, Ohio"; and (pkg.) "Sold As An Aid In The Prevention of Disease Prophylactics Contents ¼ Doz."

RESULTS OF INVESTIGATION: Examination showed that 5.5 percent of the article was defective in that it contained holes.

LIBELED: 5–29–62, N. Dist. Ohio.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it purported to possess; and 502(a)—the label statements "Sold For The Prevention of Disease Only" and "Sold As An Aid in The Prevention of Disease" were false and misleading as applied to a product containing holes.

DISPOSITION: 6–29–62. Default—destruction.

7200. **Rubber prophylactics.** (F.D.C. No. 46537. S. No. 28–802 T.)

QUANTITY: 1,086 gross at Kansas City, Mo., in possession of M & M Rubber Co.

SHIPPED: 9–14–61, from Carolina, P.R., by De Caribe Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics Package of Two M & M Rubber Co., K. C. 8, Mo. * * * Sold for the prevention of disease only."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and some of the article had been repacked by the dealer into packages as described above. The remainder of the article was in unlabeled drums.

Examination showed that 13.9 percent of those examined in the bulk drums and 11.6 percent of those examined which had been repacked, were defective in that they contained holes.

LIBELED: 11–20–61, W. Dist. Mo.

CHARGE: 501(c)—when shipped and while held for sale, the quality of the article fell below that which it purported to possess; 502(a)—the statement on the label of the repacked portion "Sold for the prevention of disease only" was false and misleading as applied to an article containing holes; and 502(b)(1)—the distributor's name on the repacked article was not qualified by the statement "distributed by."

DISPOSITION: 1–9–62. Default—destruction.

7201. **Clinical thermometers.** (F.D.C. No. 47597. S. No. 56–428 T.)

QUANTITY: 48 boxes, 24 thermometers each, at East Orange, N.J.

SHIPPED: 12–13–60 and 2–14–62, from Brooklyn, N.Y., by Puritee Thermometer Corp.

LABEL IN PART: (Box) "Two Dozen Perma-Color Certified Clinical Thermometers Stubby" and (envelope) "Certified Clinical Thermometer C–S–1–52 * * * Stubby."

RESULTS OF INVESTIGATION: Examination showed that 3 thermometers of the 24 tested failed to meet the requirements for accuracy specified in CS1–52, issued by the National Bureau of Standards.

LIBELED: 5–14–62, Dist. N.J.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess, since it did not give accurate readings; 502(a)—the labeling of the article contained false and misleading representations, namely, "Certified Clinical Thermometer C–S–1–52"; and 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 6–25–62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

7202. Formula B–13. (Inj. No. 421.)

COMPLAINT FOR INJUNCTION FILED: 12–1–61, Dist. N. Mex., against Emmett F. Stockton, t/a Stockton Laboratories, and Co., and Wise Laboratories, and Co., Albuquerque, N. Mex.

NATURE OF BUSINESS: The defendant was engaged in the business of promoting, through advertising and mail orders, the drug *Formula B–13*, offered to the public as effective for the treatment and cure of ulcers without the need for any restrictions as to diet and alcoholic consumption.

From time to time, the defendant varied the composition of *Formula B–13*, consisting essentially of a drug known as "Trinsicon" which is sold in drugstores throughout the country for the treatment of conditions unrelated to ulcers. Defendant bought the "Trinsicon" in drugstores in Albuquerque, N. Mex., and relabeled it with his own label as follows:

FORMULA B–13

Two Pulvules Contain:
Special Liver-Stomach Concentrate
(Containing Intrinsic Factor) 300 Mg.
Vitamin B–12 with Intrinsic Factor
Concentrate, U.S.P.–1 U.S.P. Unit (Oral)
Vitamin B–12 Activity Concentrate, N.F. 15 Mg.
The above Ingredients are Clinically Equivalent to 1½ U.S.P. Units of A.P.A.
Potency:
Ferrous Sulfate, Anhydrous---------- 600 Mg.
Equal to over 1 Gm. Ferrous Sulfate, U.S.P.
Ascorbic Acid (Vitamin C)---------- 150 Mg.
Folic Acid---------- 2 Mg.

60 Capsules

Obtained from extractives of suitable microbial organisms and liver and determined microbiologically against vitamin B–12 standard, the total amount, including that contained in the vitamin B–12 with intrinsic factor concentrate, U.S.P. is 30 Micrograms.
Usual Adult Dose — One pulvule two times daily, or as directed by the Physician.
Keep tightly closed and in a cool dry place.

WISE LABORATORIES, AND CO.
10205 Norman, N.E.
Albuquerque, New Mexico

*See also Nos. 7162, 7167, 7169–7174, 7177–7179, 7182–7185, 7188–7191, 7193, 7195, 7196, 7198–7201.

At times, the defendant included as part of *Formula B–13*, separate garlic capsules manufactured in New York and repacked and relabeled by defendant with a label declaring:

FORMULA B–13
Odor-free, Tasteless, sealed garlic capsules

30 Capsules
Take one every Twenty Four Hours
Take after meals for best results
Or as directed by Physician (sic)
Packed by: The Stockton Laboratories Co.
2507 Stevens Drive, N.E.
Albuquerque, New Mexico

In conjunction with the sale and distribution of *Formula B–13*, the defendant distributed certain labeling consisting of a form letter entitled "Subject: ULCERS," and other written, printed, and graphic matter.

CHARGE: The complaint alleged that the defendant caused the introduction and delivery for introduction into interstate commerce, of the drug *Formula B–13*, which was misbranded within the meaning of 502(a), in that its labeling was false and misleading since it represented, suggested, and created the impression that the drug was adequate and effective in the treatment of duodenal and gastric ulcers, whereas the drug was not adequate and effective for such purposes.

The complaint alleged further that the defendant caused the above-mentioned labeling to accompany the drug while it was held for sale after shipment in interstate commerce, which act resulted in *Formula B–13* being misbranded within the meaning of 502(a) as set forth above.

It was alleged further that, if the defendant were restrained from using the labeling complained of, he might, unless enjoined, distribute *Formula B–13* without labeling stating the diseases, conditions, symptoms, and purposes for which the drug was intended. In such case, *Formula B–13* would be misbranded within the meaning of 502(f)(1), in that its labeling would fail to bear adequate directions for use because of the omission of a statement as to all the conditions and purposes for which the drug was intended.

DISPOSITION: On 12–1–61, the defendant having consented, the court entered a permanent injunction enjoining the defendant and all persons in active concert or participation with him who receive actual notice of the decree or otherwise, from directly or indirectly doing any of the following acts with respect to *Formula B–13*, or any part thereof, or with respect to any similar drug or any drug intended for similar purposes:

A. Causing to be introduced or delivered for introduction into interstate commerce, any such drug which is misbranded because —

(1) Its labeling represents, suggests, or creates the impression that such drug is adequate and effective in the treatment of duodenal or gastric ulcers; or

(2) Its labeling fails to state all of the diseases, conditions, symptoms, and purposes for which the drug is intended to be used and for which it is represented, by any means, to the public; or

B. Causing any act to be done with respect to any such drug while it is held for sale after shipment in interstate commerce, which act results in such drug being misbranded as described above.

7203. C–Y 1717 Vitamin G, C–Y 1710A Cyroplex wafers, C–Y 1715 Vitamin E, Phosfood C–Y 1718, Cataplex A and C V–P 711–13 tablets, C–Y 1729 Cyruta wafers, and Cardiotrophin. (F.D.C. No. 44931. S. Nos. 49–098/99 P, 53–896 P, 61–901 P, 61–904 P, 68–066 P, 68–069 P.)

INFORMATION FILED: 9–28–60, E. Dist. Wis., against Vitamin Products Co., a corporation, and Royal Lee, president, Milwaukee, Wis.

SHIPPED: Between 11–24–58 and 9–10–59, from Milwaukee, Wis., to Oakland, Calif., Wayne, Pa., and St. Louis, Mo.

LABEL IN PART: (Btls.) "C–Y 1717 Vitamin G Content of Vitamin factors for which standards have been established: Riboflavin . . . 1 mg. Niacin . . . 12 mg. * * * With synergists and extracts from yeast, sprouted grain and calf brain * * * Therapeutic Foods Co., Milwaukee, Wisconsin"; "C–Y 1710A Cyroplex Concentrates from alfalfa, carrot, beef and fish liver lipoids, yeast, wheat germ, rice bran, liver, mushroom, green peas (whole plant), biologically processed corn. CARRIER MATERIAL: milk solids, wheat and oat flours. Each wafer contains 400 U.S.P. units Vitamin A, 10 U.S.P. units Vit. B_1, 20 U.S.P. units Vit. C, 100 U.S.P. units Vit. D, 25 Sherman Borquin units (60 gamma) Vit. G (ribo-flavin), 10 milligrams unsaturated fatty acids with naturally occurring associated factors * * * Therapeutic Foods Co., Milwaukee, Wisconsin"; "C–Y 1715 Vitamin E Concentrates of Vitamin factors from the juice of green peas (whole plant), and natural mixed tocopherols (Vitamin E) obtained from vegetable oils . . . 1 mg. of Chlorophyll, and 35 mgs. of Ribonucleic Acid. Carrier Materials: Liver powder, wheat germ and lettuce * * * Therapeutic Foods Co., Milwaukee, Wisconsin"; "Phosfood C–Y 1718. Active Ingredients: Ortho-phosphoric acid, Phytin from cereal sources. Carrier Material: Raw sugar, corn starch, and gum arabic * * * Therapeutic Foods Company, Milwaukee, Wisconsin"; "Cataplex A and C Vitamins A and C V–P 711–13 Each tablet contains 750 U.S.P. units of Vitamin A and 100 U.S.P. units of Vitamin C with naturally associated vitamin and enzyme factors from Alfalfa, Carrot, Mushroom, Green Buckwheat Leaf, Bone Marrow, Beef Kidney and Fish Liver Lipoids. Carrier Materials: Rice Bran, Oat Flour, Fresh Bone Flour, and Anhydrous Honey * * * Vitamin Products Co., Milwaukee, Wisconsin"; "C–Y 1729 Cyruta Dehydrated extract of buckwheat seed and green leaf. Each wafer contains 90 mgm. inositol * * * Therapeutic Foods Co., Milwaukee, Wisconsin"; "Cardiotrophin Cytotrophic Extract of Beef Heart * * * Standard Process Laboratories, Milwaukee, Wisconsin Made in U.S.A."

ACCOMPANYING LABELING: Looseleaf folder entitled, on cover, "Therapeutic Foods Company:" and, on first page, "Doctor's Books An Introduction to Clinical Nutrition" and looseleaf folder entitled "Therapeutic Food Manual"; booklets entitled "Schedule of Recommendations for Specific conditions of Malnutrition" and "Applied Trophology * * * 1958, Volume 2—numbers 1–12"; looseleaf folders entitled "Issues on Relations of Vitamins to Heart Disease" and "Vitamin News"; booklet entitled, on cover, "Standard Process Laboratories" and, on first page, "Protomorphogens Non-Vitamin Food Factors"; looseleaf folder entitled, on cover, "Vitamin Products Company" and, on first page, "Product Information for Doctors"; and looseleaf folder entitled, on cover, "Therapeutic Foods Company" and, on first page, "Product Information for Doctors."

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the articles were adequate and effective for the prevention and treatment of the following diseases and conditions:

C-Y 1717 Vitamin G—alopecia, Anders' disease, angina pectoris, asthma, astigmatism, biliary stasis, brain concussion, Buerger's disease, cancer, cataracts, cerebral hemorrhage, cerebral palsy, cerebral thrombosis, chorea, cirrhosis of the liver, conjunctivitis, coronary insufficiency, diabetic retinitis, diabetes mellitus, enlarged heart, epilepsy, fibroid tumors, gastric ulcers, heart block, herpes simplex, herpes zoster, hypertension, hypertrophy of the heart, liver diseases, mastitis, mitral stenosis, multiple sclerosis, nephritis, neuritis, neuromuscular disorders, nose polyps, osteoarthritis, Paget's disease, palsy, Parkinson's disease, pernicious anemia, prevention of heart disease, Raynaud's disease, rheumatoid arthritis, sciatica, shock, sterility, stroke, and varicose veins;

C-Y 1710A Cyroplex wafers—abortion, adrenal insufficiency, amenorrhea, ascites, brain concussion, brain dysfunction, brucellosis, Buerger's disease, bursitis, cancer, cataracts, cerebral palsy, chorea, cirrhosis of the liver, conjunctivitis, cryptorchism, cystitis, deafness, diabetes mellitus, disc lesions, Dupuytren's disease, emphysema, endocervicitis, epilepsy, febrile diseases, fibroid tumors, gallbladder diseases, gastric ulcers, gingivitis, goiter, gout, gynecomastia, heart diseases and conditions, hemorrhoids, hernia, herpes simplex, herpes zoster, hypertension, hyperthyroidism, hypotension, intestinal worms, leg ulcers, leukopenia, leukoplakia, lymph node infections, malaria, mastitis, mucous colitis, multiple sclerosis, muscular dystrophy, myasthenia gravis, myocarditis, myositis ossificans, nephritis, osteoarthritis, palsy, Peyronie's disease, phlebitis, poliomyelitis, prostate disease, rheumatic fever, sciatica, shock, sinusitis, strictures, stroke, telangiectasis, tonsillitis, tuberculosis, varicose veins, Vincent's infection, and virus infections;

C-Y 1715 Vitamin E—abortion, acne, acute and subacute vascular obstructions, acute glomerulonephritis, arteriosclerosis, atrophic arthritis, Bell's palsy, Buerger's disease, bursitis, cancer, coronary occlusion, coronary thrombosis, Dupuytren's contracture, diabetes mellitus, exfoliative dermatitis, febrile diseases, fibroid tumors, gastric ulcers, grippe, heart failure, hernia, herpes zoster, influenza, leukoplakia, multiple sclerosis, muscular atrophy, muscular dystrophy, myocardial degeneration, neuritis, paralysis of young, peripheral thrombosis, Peyronie's disease, phlebitis, prevention of heart disease, sinusitis, sterility, Sydenham's chorea, thromboangiitis obliterans, thrombocytopenia, thrombophlebitis, urethral stricture, and varicose veins;

Phosfood C-Y 1718—Buerger's disease, bursitis, cataracts, cerebral apoplexy, deafness, diabetic ulcers, diarrhea, emphysema, gastric ulcers, gallbladder diseases, glaucoma, hyperthroidism, hypertension, hypotension, heart diseases and conditions (coronary disease, angina pectoris, bradycardia, myocarditis), kidney stones, leukocytosis, leukopenia, neuritis, osteoarthritis, phlebitis, varicose ulcers, and varicose veins;

Cataplex A and C V-P 711-13 tablets—angina pectoris, asthma, Buerger's disease, bronchitis, bursitis, cerebral hemorrhage, cataracts, fibroid tumors, glaucoma, glomerulonephritis, gastric uclers, heart diseases and conditions (bacterial endocarditis, stenosis due to scars from rheumatic fever), hypertension, influenza, leukopenia, Meniere's disease, mumps, nose polyps, nephritis, osteoarthritis, osteoporosis, ovarian tumors, Paget's disease, phlebitis, pyorrhea, rheumatic fever, staphylococcus infections, streptococcus infections, undulant fever, varicose veins, and Vincent's infection;

C-Y 1729 Cyruta wafers—Anders' disease, arteriosclerosis, blurred vision, cancer, cataracts, cirrhosis of the liver, diabetic retinitis, diabetes mellitus, erysipelas, glaucoma, gastric ulcers, hypertension, malignant hypertension,

Paget's disease, prostate hypertrophy, paroxysmal tachycardia, and rheumatoid arthritis;

Cardiotrophin—adrenal insufficiency, all forms of heart disease, arteriosclerosis, asthma, diabetes mellitus, and hernia.

PLEA: Nolo contendere by Vitamin Products Co., to the counts involving all of the above-mentioned products and by Royal Lee to the counts involving *C–Y 1717 Vitamin G and C–Y 1710A Cyroplex wafers.*

DISPOSITION: 4–23–62. Royal Lee—imprisonment for 1 year (suspended), and probation for 3 years; Vitamin Products Co.—$7,000 fine.

7204. Vitamin products. (F.D.C. No. 47439. S. Nos. 3–538/39 T, 4–946/55 T, 4–957/59 T.)

QUANTITY: 398 display-type pkgs., each containing 1 30-capsule canister and 1 individually ctnd. 100-capsule btl., of *Hi-Potency Geriatric Formula;* 1,360 display-type pkgs., each containing 1 30-tablet canister and 1 individually ctnd. 100-tablet btl., of *Hi-Potency therapeutic M;* 2,561 display-type pkgs., each containing 1 30-tablet canister and 1 individually ctnd. 100-tablet btl., of *Hi-Potency vitamins and minerals;* 2,778 display-type pkgs., each containing 1 30-capsule canister and 1 individually ctnd. 100-capsule or 250-capsule btl., of *Hi-Potency super vitamins;* 312 100-capsule btls. (25,000 units), and 270 100-capsule btls. (50,000 units), of *Hi-Potency vitamin A;* 159 100-capsule btls. of *Hi-Potency vitamin* B_1*;* 131 (25 mcg.) and 51 (10 mcg.) 100-tablet btls. of *Hi-Potency vitamin* B_{12}; 1,381 100-tablet btls. of *Hi-Potency vitamin C,* at Washington, D.C.

SHIPPED: Between 12–29–61 and 2–9–62, from Allegan, Mich., by L. Perrigo Co.

LABEL IN PART: (Btl. and ctn.) "Hi-Potency Geriatric Formula * * * Blake Pharmacal Co., Allegan, Michigan, Distributors"; "Hi-Potency Therapeutic M * * * Blake Pharmacal Co."; "Hi-Potency Vitamins and Minerals * * * Blake Pharmacal Co."; "Hi-Potency Super Vitamins * * * Blake Pharmacal Co."; (btl.) "Hi-Potency Vitamin A Capsules 25,000 [or "50,000"] U.S.P. Units Synthetic Vitamin A Palmitate * * * Blake Pharmacal Company"; "Hi-Potency Vitamin B_1 Thiamin Chloride * * * Blake Pharmacal Company"; "Hi-Potency Vitamin B_{12} Cobalamin Conc. 25 mcg. [or "10 mcg."] Vitamin B_{12} Activity * * * Blake Pharmacal Company"; "Hi-Potency Vitamin C Ascorbic Acid * * * Blake Pharmacal Company"; and (display pkg.) "30-Day Supply of Vitamins in this beautiful Toleware Table Canister With Each Bottle."

ACCOMPANYING LABELING: Booklets entitled "The Who * * * What * * * Why * * * When of Vitamins."

LIBELED: 4–9–62, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of colds, infections, pernicious anemia, faulty bone and tooth development, cramps in calf muscles, nervousness, heart trouble, insomnia, constipation, vaginitis, sore tongue, sore gums and sore mouth, lack of appetite, difficulty in walking, cutaneous hemorrhages, muscle degeneration, stunted growth, susceptibility to infection, enlargement of wrists, knees, and ankles, and improper bone and muscle development.

DISPOSITION: 5–14–62. Consent—claimed by L. Perrigo Co. and released under bond for relabeling.

7205. **Pan A–C capsules.** (F.D.C. No. 47450. S. No. 62–768 T.)

QUANTITY: 39 250-capsule btls. and 83 100-capsule btls. at Bloomington, Minn.

SHIPPED: Between 8–23–61 and 12–13–61, from Holland, Mich., by The DePree Co.

LABEL IN PART: (Btl. and ctn.) "DePree Pan A–C capsules * * * therapeutic levels of vitamins A, C, and pantothenic acid * * * Dist. by Nutritional Products Division The DePree Company, Holland, Michigan."

LIBELED: 4–16–62, Dist. Minn.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective as an adjunctive nutritional supplement for the treatment of severe burns and extensive sunburn, allergic conditions, hay fever, ivy poisoning, contact dermatitis, urticaria, hives, inflammation, and injury; and for treatment of metabolic disorders, severe or prolonged pain, physical exhaustion, emotional distress, prolonged illness and convalescence, conditions requiring or due to surgery, conditions during therapy with ACTH, cortisone, and related hormones, and nonspecific effects of severe or continued stress.

DISPOSITION: 5–29–62. Default—destruction.

7206. **Vitamins, minerals, and other preparations.** (F.D.C. No. 45006. S. Nos. 35–196 R, 35–198/205 R, 35–207/212 R.)

QUANTITY: 8 100-tablet btls. of *vitamin A*, 5 100-tablet btls. of *vitamin* B_1, 3 100-tablet btls. of *vitamin* B_{12}, 1 100-tablet btl. of *vitamin B complex with iron and vitamin C*, 24 100-tablet btls. of *vitamin C*, 13 100-tablet btls. of *vitamin E*, 1 100-tablet btl. of *One Daily small multiple vitamins*, 4 100-tablet btls. of *therapeutic vitamins and minerals*, 4 60-tablet btls. of *super potency vitamins and minerals*, 2 90-capsule btls. of *Prenatal capsules*, 31 100-capsule btls. of *lecithin*, and 59 100-tablet btls. of *citrus bioflavonoids with vitamin C*, at New York, N.Y., in possession of Textile Mart, Inc., or the related firms, Jay Norris Co. and Norris Nutritions.

SHIPPED: Between 7–8–60 and 10–18–60, from Elizabeth, Jersey City, and Newark, N.J.

LABEL IN PART: "Vitamin A" (formula 856 and formula 876), "Vitamin B_1" (formula 875), "Vitamin B_{12}" (formula 858), "Vitamin B Complex with Iron & Vitamin C" (formula 851), "Vitamin C" (formula 857 and formula 865), "Vitamin E" (formula 866 and 867), "Therapeutic Vitamins & Minerals" (formula 852), "One Daily Small Multiple Vitamins" (formula 853), "Super Potency Vitamins & Minerals" (formula 864), "Prenatal Capsules" (formula 859), "Lecithin Capsules" (formula 868), "Citrus Bioflavonoids with Vitamin C" (formula 860).

ACCOMPANYING LABELING: Booklets entitled "Norris Wholesale Vitamin Catalog #606V."

RESULTS OF INVESTIGATION: The accompanying labeling had been printed locally and used in promoting sales of the articles while held for sale after shipment in interstate commerce.

LIBELED: 10–18–60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations with respect to the articles, as follows:

Vitamin A (formula 856 and 876)—that poor growth, unhealthy skin, poor eyesight, infections and colds are often due to deficiencies of vitamin A, and

that use of the article would correct and prevent such diseases, symptoms, and conditions;

Vitamin B_1 (formula 875)—that loss of appetite and muscle tone, vague aches and pains, nervousness, and digestive upsets are often due to deficiencies of vitamin B_1, and that use of the article would correct and prevent such diseases, symptoms, and conditions;

Vitamin B_{12} (formula 858)—that poor growth, poor appetite, and nutritional anemia are usually and frequently caused by deficiencies of vitamin B_{12} in the diet, and that use of the article would correct and prevent such diseases, symptoms, and conditions;

Vitamin B complex with iron and vitamin C (formula 851)—that tired, washed-out feeling, tense and unsteady nerves, lost vitality, unhealthy gums, teeth, bones, and blood vessels, are usually and frequently caused by deficiencies of the vitamin B complex, iron, and vitamin C in the diet, and that use of the article would correct and prevent such diseases, symptoms, and conditions;

Vitamin C (formula 857 and formula 865)—that unhealthy gums, teeth, bones, and blood vessels, and fatigue, are usually and frequently caused by a deficiency of vitamin C in the diet, and that use of the article would correct and prevent such diseases, symptoms, and conditions;

Vitamin E (formula 866 and formula 867)—that sterility, nonpregnancy, and muscular and nervous disorders, are usually and frequently caused by deficiencies of vitamin E in the diet, and that use of the article would correct and prevent such diseases, symptoms, and conditions;

One Daily small multiple vitamins (formula 853); *therapeutic vitamins and minerals* (formula 852); *super potency vitamins and minerals* (formula 864); and *Prenatal capsules* (formula 854)—that poor growth, unhealthy skin, poor eyesight, infections, colds, loss of appetite and muscle tone, vague aches and pains, nervousness, digestive upsets, nutritional anemia, tired, washed-out feeling, tense and unsteady nerves, lost vitality, poor resistance to illness, unhealthy gums, teeth, bones, and blood vessels, fatigue, sterility, nonpregnancy, and muscular and nervous disorders are usually and frequently caused by deficiencies of vitamins A, B_1, B_{12}, B complex, C, and E in the diet, and that use of the articles would correct and prevent such diseases, symptoms, and conditions;

Therapeutic vitamins and minerals (formula 852)—that the article was an adequate and effective treatment for insomnia and loss of weight;

Super potency vitamins and minerals (formula 864)—that the article was an adequate and effective treatment for nervous tension and lowered resistance to illness, and that it would help in metabolism of fat, fight stress, help digestion, and relax nerves;

Prenatal capsules (formula 859)—that the article was an adequate and effective treatment for leg cramps, anemia, tooth decay, weak blood vessels, and nervous tension, and that the article would help to combat nausea;

Lecithin capsules (formula 868)—that lecithin is a valuable addition to the diet; that by providing phospholipids to the body, lecithin was an important dietary factor because phospholipids are present in all body tissues; that lecithin, when used to supplement the diet, performs the function of aiding in the utilization and transportation of fat; preventing and removing fatty deposits of atherosclerosis; bringing about the proper metabolism of fat; controlling hypercholesteremia, and aiding fat digestion;

Citrus bioflavonoids with vitamin C tablets (formula 860)—that the article was an adequate and effective treatment for the common cold, and, because of the vitamin C, for unhealthy gums, teeth, bones, and blood vessels, and fatigue,

and that use of the article would correct and prevent such conditions and be helpful in healing wounds and preventing anemia.

The libel alleged also that the *Prenatal capsules* (formula S59), *One Daily small multiple vitamins* (formula S53), *super potency vitamins and minerals* (formula S64), *vitamin E capsules* (formula S66 and formula S67), and *therapeutic vitamins and minerals* (formula S52), were misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 11–8–61. Consent—destruction.

7207. Hilcoa food supplements. (F.D.C. No. 45527. S. Nos. 85–683/4 R.)

QUANTITY: 146 ctns., each containing 336 *vitamins-minerals tablets* and 120 *protein with lecithin tablets*, at North Kansas City, Mo.

SHIPPED: On 2–16–61 and 3–7–61, from Oakland and Los Angeles, Calif., by Hilcoa Co., San Jose, Calif., and Toland Labs., Burbank, Calif.

LABEL IN PART: (Ctn.) "Hilcoa Improved Food Supplements Natural or Organic Vitamins and Minerals including Protein with Lecithin Bonus Paks * * * 336 Vitamin-Mineral Tablets 120 Protein-Lecithin Tablets * * * The Hilcoa Company."

ACCOMPANYING LABELING: A distributor's "Handbook" ("Hilcoa" on black cover); leaflets entitled "Hilcoa Highlights Nov–Dec 1960 Season's Greetings" and "Food Comes First"; circular entitled "Is Hilcoa for You?"; and distributor's "Sales Manual" ("Hilcoa" on red cover).

LIBELED: 3–27–61, W. Dist. Mo.; amended libel 5–18–61.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of nervousness, loss of appetite, neuritis, loss of muscle tone, digestive upsets, diarrhea, vague aches and pains, fatigue, irritability, headache, dizziness, dryness of the hair and skin, mental depression, insomnia, indigestion, loss of weight, constipation, weakness, reddening of the eyes, sores about the angles of the mouth, swelling and redness of the tongue, inflammation of the mouth, dental caries, anemia, defective teeth and gums, pyorrhea, gum infections, loss of appetite, local hemorrhages of nose, mouth, and gums and about the face, improper coagulation of the blood, muscular soreness, spasms and muscular numbness, tingling of the muscles of pregnant women, lack of energy, palpitation of the heart, and excessive bleeding from minor wounds; and that the articles were adequate and effective for good, radiant health, and proper growth.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4–25–62. Default—destruction.

7208. Special 10 with B_{12} multivitamin capsules and Geriatric Formula multivitamin capsules. (F.D.C. No. 44745. S. Nos. 8–480 R, 8–645 R.)

QUANTITY: 120 cases, 72 100-capsule btls. each, of *Special 10 with B_{12};* and 629 30-capsule jars of *Geriatric Formula*, at Rochester, N.Y., in possession of East Vitamin Products.

SHIPPED: 5–31–60, from Newark, N.J.

ACCOMPANYING LABELING: Leaflets entitled: "East Multi Vitamins selected by Industry for employee Health, Value and Quality," "This is Your Order Form," "East Vitamins Will Help Your Employees Maintain Good Health," "A Recent Newspaper Editorial," "A Reader's Digest Reprint How to Prolong the Prime

of Life," "Read what the Wall Street Journal Has to Say About Vitamins," "Dear Friends: So many folks have asked . . .," "This Certificate Worth $1.00," and "Order Form . . . Geriatric Formula."

RESULTS OF INVESTIGATION: The accompanying labeling had been prepared by the dealer and used in promoting sales of the articles.

LIBELED: 7–29–60, W. Dist. N.Y.

CHARGE: *Special 10 with* B_{12}, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of rundown, tired feeling, loss of pep and vigor, premature aging, colds, minor ailments, influenza and other respiratory diseases, heart disease, nervousness, gastroenteritis, low back pains, chronic ailments, senile dementia, rheumy, inflamed eyes, feebleness, digestive, nervous, and mental ailments, abnormal heart action, and damaged liver, and to produce a feeling of new life, vigor and zest for living, general well-being, feeling of freshness, vital and glowing health; to feel peppier, more alert, and have a new sense of confidence; to produce vitality, resistance to infection, sound teeth, nerves, and bones, appetite, sound muscle and tissue, skin, health, and proper functioning of the intestinal tract.

Geriatric Formula, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tuberculosis, muscular ills, nerve disorders, high blood pressure, pernicious anemia, mental disorders, alcoholism, tired, dragged-out conditions, premature aging, senile dementia, rheumy, inflamed eyes, feebleness, digestive, nervous, and mental ailments, abnormal heart action, damaged liver, heart disease, fat in liver, coronary heart attacks, strokes, disease of the kidneys, and cirrhosis of the liver; and to produce clotting of blood, more rapid recovery from disease, shock, and surgery, and increased mental and physical energy and alertness; to make one feel stronger and happier; feel better in mind and body; to transform the dull pattern of mere existence into a life of rich, radiant happiness; would benefit distressing symptoms due to faulty nutrition; and that it was absolutely indispensable for proper health.

The libel alleged also that both articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 9–12–60, the claimant, Main Electric Co., Inc., d/b/a East Vitamins, Rochester, N.Y., having consented, the court entered a decree of condemnation, and the articles were released under $5,000 bond to the claimant for the purpose of bringing the articles into compliance with the law.

On 10–9–61, a motion was filed by the Government for forfeiture of the bond on the ground that the claimant violated the terms of the decree and bond in that it failed to retain intact the entire lot of seized goods and seized literature, and disposed of the seized vitamins and a portion of the literature without notification to, or authorization by, the Department of Health, Education, and Welfare.

On 5–31–62, after a hearing, and in accordance with the court's findings of fact and conclusions of law, judgment was entered, pursuant to which the $5,000 bond was declared forfeit because claimant failed to abide by the conditions of the bond; $4,000 of the forfeiture was remitted because of the lack of evil intent by the claimant to violate the conditions of the bond; and the Government was granted a $1,000 money judgment.

7209. Safflower oil. (F.D.C. No. 47422. S. Nos. 42–013 T, 42–015 T.)

QUANTITY: 37 1-pt. btls., 51 1-qt. btls., and 10 8-oz. btls., at Easton, Pa., in possession of Forks Township Pharmacy.

SHIPPED: Between 2–2–62 and 2–21–62, from Phillipsburg, N.J., and Lynbrook, N.Y.

LABEL IN PART: (Pt. & qt. btls.) "Health Foods Saf-Flower Oil Contains 74% to 79% Poly-Unsaturates"; (strip label attached to btls.) "Ask Your Doctor About The Value of Saf-Flower Oil Richest in Poly-Unsaturates"; (tag on btls.) "Try * * * Safflower Oil Margarine * * * Best For Low Cholesterol Diets"; (8-oz. btl.) "Safflower Oil * * * repacked by Fork's Township Pharmacy * * * Easton, Penna."

ACCOMPANYING LABELING: Books entitled "Calories Don't Count" by Herman Taller, M.D., and placard reading in part "How to Lose Weight Without Even Trying Dr. Herman Taller's Sensational New Book 'Calories Don't Count'."

RESULTS OF INVESTIGATION: The *safflower oil* in the 8-oz. bottles was repacked by the dealer from bulk cans.

The above-mentioned books were ordered by the dealer from a book distributor and the placard was prepared by the dealer.

LIBELED: 4–3–62, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the control of body weight and to reduce and to maintain slimness, even though consuming many thousands of calories daily without regard to the total caloric intake; to lower and control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis, heart disease, diabetes, and heartburn; and to improve the complexion; increase resistance to colds and sinus trouble; promote health; and to increase sexual drive.

DISPOSITION: 5–9–62. Default—destruction.

7210. Easy-Slim timed disintegration capsules. (F.D.C. No. 43475. S. No. 38–488 P.)

QUANTITY: 65 boxes, each containing 30 capsules, at Springfield, Mo.

SHIPPED: 9–21–59, from Little Rock, Ark., by Sentinel Laboratories, Inc.

LABEL IN PART: "30 Day Supply of Easy-Slim Timed Capsules A New Approach To Weight Reduction. Each capsule contains Phenylpropanolamine HCl 50 Mg. In A Specially Prepared Form to Give Sustained Blood Levels For a Period of 6 to 10 Hours. Manufactured For Sentinel Laboratories, Incorporated, Little Rock, Arkansas."

ACCOMPANYING LABELING: Counter display card reading in part "Only one Easy-Slim each day Reduce craving for food—Lose that dangerous bulge—Sentinel Laboratories"; window streamer reading "Easy-Slim"; and Easy-Slim Club cards reading in part "Easy-Slim Club Complimentary Pass."

LIBELED: 10–13–59, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the name "*Easy-Slim*" and its labeling contained false and misleading representations that the article was an effective treatment for obesity.

DISPOSITION: 1–25–60. Default—destruction.

7211. Slimerall reducing capsules. (F.D.C. No. 44186. S. No. 86–464 P.)

QUANTITY: 50,000 capsules at Pittsburgh, Pa., in possession of Pennex Products Co., Inc.

SHIPPED: 12–4–59, from Hempstead, N.Y.

LABEL IN PART: (Pkg.) "Slimerall Reducing Capsules An Aid to Appetite Control * * * Each Capsule Contains: Phenylpropanolamine Hydrochloride 50 mg. Vitamin B_1 (Thiamin Chloride) 2 mg. Iron (From Iron Sulfate) 10 mg. * * * Distributed by Pennex Products Co., Inc., Pittsburgh, Pa."

ACCOMPANYING LABELING: Folder entitled "Stay Slimmer, Trimmer with Slimerall Reducing Capsule Plan"; display carton labeled in part "Slimerall Reducing Capsules"; cardboard sleeve fitting over the display cartons labeled "1 Doz. Plastic Boxes Slimerall Reducing Capsules"; and wall banner entitled "Safe Effective Reduce the Easy Way! Slimerall."

RESULTS OF INVESTIGATION: The article had been shipped in bulk, in granular form, to the dealer and encapsulated and packaged into 200 cartons, each carton containing 12 packages of 21 capsules each, labeled as above.

The accompanying labeling had been prepared locally for the dealer.

LIBELED: 1–18–60, W. Dist. Pa.; libel amended 1–25–60.

CHARGE: 502(a)—while held for sale, the name of the article, *Slimerall reducing capsules*, and its accompanying labeling, contained false and misleading representations that the article was adequate and effective in controlling the appetite and to reduce and control weight.

DISPOSITION: 4–18–60. Default—destruction.

7212. Sea-Con. (F.D.C. No. 46286. S. No. 69–087 R.)

QUANTITY: 135 btls. at Rochelle, Ill.

SHIPPED: 3–25–61 and 4–21–61, from Columbia, S.C., by Sea-Con, Inc.

LABEL IN PART: (Btl.) "Contents One Pint Sea-Con Concentrated Ocean Water Sterilized-Pasteurized * * * is highly concentrated * * * Prepared by Sea-Con, Inc. Columbia, S.C. * * * Take one or two tablespoonsful daily * * * Warning:" and (ctn.) "Sea-Con You May Add Life To Years Add Years to Life * * * a specially prepared concentration from the sea. The only known source of all 44 water soluble trace elements."

LIBELED: 8–21–61, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article possessed special therapeutic and dietary supplementation properties that will "add life to years" and "add years to life"; that it contained 44 water-soluble trace elements beneficial to the user; and that the article had certain medical properties.

DISPOSITION: On 9–28–61, the claimant, H. D. Campbell Co., Rochelle, Ill., filed an answer denying that the article was misbranded, and thereafter the Government served written interrogatories upon the claimant. On 6–1–62, the claimant having failed to answer such interrogatories, the court entered a default decree providing for condemnation and destruction of the article.

7213. Sea-Con. (F.D.C. No. 45356. S. No. 46–237 R.)

QUANTITY: 67 1-pt. btls. at Charlotte, N.C.

SHIPPED: 11–16–60, from Columbia, S.C., by Sea-Con, Inc.

LABEL IN PART: "Sea-Con A Specially Prepared Concentration From The Sea Minerals in Sea Water Normally Contain 44 Trace Elements as Listed Hereon * * * Manufactured by Sea-Con, Inc., P. O. Box 3115, Columbia, S.C."

ACCOMPANYING LABELING: Booklets entitled "The Story of Sea-Con."

LIBELED: 1–20–61, W. Dist. N.C.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for arthritis, palsy, Parkinsonism, and deficiency ailments; and that consumption of sea water would help prevent disease, prolong life, provide significant benefits to health, delay old age, and result in "health and happiness."

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–31–61. Default—destruction.

7214. Cyclodrine tablets. (F.D.C. No. 44143. S. No. 70–354 P.)

QUANTITY: 35 90-tablet btls. at Riverside, N.J.

SHIPPED: 11–11–59, from Philadelphia, Pa., by Hance Bros. & White Co.

LABEL IN PART: (Btl.) "Cyclodrine Each tablet contains Cyclodrine* 25 mg. *Hance Brand Of Phenylpropanolamine Hydrochloride. Hance Bros. & White Co. Philadelphia, Penna."

ACCOMPANYING LABELING: Leaflets entitled "Cyclodrine," and display cartons reading in part "Overeating? Overweight? Take Cyclodrine."

LIBELED: 12–31–59, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as an appetite depressant and in the management and treatment of obesity.

DISPOSITION: On 2–18–60, Hance Bros. & White Co., claimant, filed an answer denying that the article was misbranded. Thereafter, the Government filed a motion for summary judgment, which motion was denied by the court on 3–17–61. On 5–15–62, the court found that the article was misbranded and entered a decree of condemnation and destruction.

7215. Gonsertron device. (F.D.C. No. 43539. S. No. 79–739 P.)

QUANTITY: 31 units (cabinet and chair) and a number of additional chairs, at Essexville, Bay City, Royal Oak, Monroe, Dearborn, and Tawas City, Mich., in possession of Gonsertron Corp., and Gonsertron health centers.

SHIPPED: Various component parts of the device had been shipped on unknown dates from Marion, Ill., Marengo, Ill., San Bernardino, Calif., Flint, Mich., Venterbrook, Conn., West Concord, Mass., Brooklyn, N.Y., and Middletown, Conn., and were used in the manufacture of the device by the Gonsertron Corp., Essexville, Mich.

LABEL IN PART: (Metal plate on cabinet) "Gonsertron Gonsertron Corporation."

ACCOMPANYING LABELING: Pamphlets entitled "Gonsertron Therapy – A new Concept in the Field of Electrotherapy."

RESULTS OF INVESTIGATION: Examination indicated the article to be a console-type cabinet enclosing various electrical components, including capacitors, oscillator tubes, rheostats, rectifiers, ammeters, timers, autotransformers, pilot lights, and lamps. The control panel contained "on-off" switches, ammeters, timer dial, variable transformer control unit, and light indicators. Electrodes extended from the cabinet to a special chair containing a metal plate in the padding of the back support. In operation, the cabinet was connected to 110-volt house current and through manipulation of the panel controls the electronic circuit emitted radio-frequency waves which were intended to be transmitted through the body of a person sitting in the chair.

LIBELED: 9–24–59, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for relieving all forms of arthritis, neuritis, asthma, bursitis, psoriasis, bronchitis, rheumatism, prostate trouble, sciatica and nervous tension; for stimulating cells of the tissues of the body to throw off accumulated waste products and take on nourishment; and for stimulating and reactivating every cell in every tissue of the body, causing the cells and tissues to become "normal."

DISPOSITION: On 10–9–59, Gonsertron Corp., claimant, filed a motion for dismissal of the libel. On 11–4–59, after consideration of briefs of counsel, the court handed down the following opinion:

LEVIN, *District Judge:* "This is a motion to dismiss the Government's libel of information, filed pursuant to 21 U.S.C., Sec. 334, against an electrotherapy device consisting of '31 units (cabinet and chair), more or less, labeled (metal plate on cabinet) "Gonsertron Corporation," an unknown number of additional chairs, and pamphlets entitled "Gonsertron Therapy – A New Concept in the Field of Electrotherapy." '

"The accused device was manufactured by the Gonsertron Corporation in Michigan. Nine component parts received by the corporation from various states in the union were used in the manufacturing process. These component parts are in common use in industry. None of them were made to the specifications of the manufacturer of the device. The device was not sold or held for sale outside of the State of Michigan.

"Sec. 334(a) of 21 U.S.C. provides that a misbranded device may be proceeded against on libel of information and condemned in any District Court of the United States within the jurisdiction of which the article is found 'when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce.'

"The Government agrees that the manufactured device was not introduced in interstate commerce or held for sale in interstate commerce. It contends, however, that Sec. 321(h) of 21 U.S.C. defines device to mean 'instruments, apparatus, and contrivances, including their components, parts, and accessories,' and therefore concludes that '* * * since some of the components used in the manufacture of the device were transported in interstate commerce, the device must also be considered to have been introduced in interstate commerce.' I do not so interpret Sec. 321(h), nor do any of the cases cited by the Government support its position.

"Moreover, if Sec. 321(h) were construed to give this Court jurisdiction by virtue of the shipment of the components to Michigan, grave doubt would exist as to the power of the Legislature to do so. For example, in *Ewing-Von Allmen Dairy Co.* v. *C and C Ice Cream*, (C.C.A. 6) 109 F. 2d., 898, 900, the Court states:

> The ingredients which came from without the state ceased to be a part of interstate commerce when manufactured and sold in Kentucky. The sales in appellants' retail stores were entirely of a local nature, made after all transportation, local and interstate, had ceased, and were beyond the regulatory power of Congress over interstate commerce.

See, also, *Lawson* v. *Woodmere*, 120 F. Supp. 267.

"An order will be entered dismissing the libel of information."

In accordance with the above opinion, the court, on 11–4–59, entered an order dismissing the libel with prejudice and quashing the monition of seizure.

7216. Micronaire device. (F.D.C. No. 43943. S. Nos. 64–216/7 P, 90–604/5 P.)

QUANTITY: 4 Senior Models and 27 Junior Models at Providence, R.I., in possession of Outlet Co.

SHIPPED: 8–27–59 and 11–9–59, from Boston, Mass., by Micronaire EMP Corp.

LABEL IN PART: "Micronaire Model 400 [or "425"] and "Micronaire Jr. Model KA."

ACCOMPANYING LABELING: Leaflets entitled "Now-Rid the Air of Impurities With the New Micronaire," "Electrostatic Precipitation," and "Guaranteed Relief From the Effects of"; and a placard prepared by the dealer.

RESULTS OF INVESTIGATION: Photographs and the literature indicated the article to be a portable, box-type cabinet containing an electric motor-driven fan which caused room air to flow through an electrostatic field set up between a series of particle-collection plates. The labeling stated that dust particles in the air are electrically charged and were attracted to the collection plates of opposite electrical polarity and thus removed from the air.

LIBELED: 12–7–59, Dist. R.I.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the article contained statements which represented and suggested that the article was an adequate and effective treatment for relieving hay fever, perennial rhinitis, and asthma; for providing "99.2% positive protection against Hay fever, Sinus, Asthma, and other airborne allergies"; for stopping allergy agonies; and for promoting health, which statements were false and misleading since the article was not an adequate and effective treatment for such conditions, and was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: The article was claimed by Micronaire Electro Medical Products Corp. The case was transferred, on 1–4–60, to the District of New Jersey. Written interrogatories were filed by the Government on or about 5–1–60, and, on 12–5–60, a consent decree of condemnation was entered and was amended on 1–4–61.

Two of the devices were delivered to the Food and Drug Administration and the remainder were destroyed.

7217. **Mattress covers.** (F.D.C. No. 42514. S. No. 25–288 P.)

QUANTITY: 8 full-size and 4 twin-size at Minneapolis, Minn.

SHIPPED: 10–7–58, from Muskegon, Mich., by Dr. Wenger & Associates, Ltd.

LABEL IN PART: (Device) "Dr. Wenger's Health Sentinel Original-Automatic" and (ctn.) "Dr. Wenger's Original 'Health Sentinel' Medically Approved Automatic Contour Mattress Cover Controlled Bed Warmth For Young & Old."

ACCOMPANYING LABELING: Leaflet in carton "The Health Sentinel You Sleep On It—Not Under It" and leaflets entitled "She Gets A Sound Sleep Every Night."

RESULTS OF INVESTIGATION: The literature and photographs indicated that the article was similar to a mattress pad, but contained a heating element.

LIBELED: 11–26–58, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for insomnia, nervousness, arthritis, rheumatism, aches and pains, and common colds.

DISPOSITION: The article was claimed by Dr. Wenger & Associates, Ltd., Chicago, Ill. The case was transferred to the Northern District of Indiana on 1–23–59. Written interrogatories were filed by the Government on 6–23–60. On 1–13–61, a consent decree was entered and the articles were destroyed.

7218. **Air purifier device.** (F.D.C. No. 47207. S. Nos. 5–249/50 T.)

QUANTITY: 6 individually ctnd. devices, 3 small and 3 large, at Baltimore, Md.

SHIPPED: 4–28–61, from Providence, R.I., by Abbey Chemco, Inc.

LABEL IN PART: (On small device) "Thunderbolt Air-Purifier-Refresher" and (on ctn. of large device) "Thunderbolt Air Purifier-Air Refresher Mfg. by Abbey Chemco Inc. * * * Providence, R.I."

ACCOMPANYING LABELING: Leaflets entitled "Thunderbolt Air Purifier Air Refresher" and a reprint of an article from "Reader's Digest" magazine entitled "Ions Can Do Strange Things To You."

RESULTS OF INVESTIGATION: Photographs and examination indicated that the device consisted of a metal box, about 5" x 5" x 15" (small) or 5" x 5" x 30" (large) in length, painted grey, with a series of louvres on the side of the small one and on top of the large one. Each device had an "on-off" switch, and the large one also had a regulating switch. There was a long cord for connecting to a source of electric power. Inside the box was a glass tube containing a small amount of mercury, and around part of the tube was a metal mesh piece. The tube and the metal mesh were connected to a transformer, also inside the box. When the device was turned on, a silent electrical discharge was created between the tube and the metal mesh. This discharge created ozone in the air.

LIBELED: 3–8–62, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that negative ions were powerful germicidal and oxidizing agents which must be replaced indoors, by use of the device; that the device would kill airborne bacteria and eliminate smoke and offensive odors, relieve the discomfort of asthma and hay fever, and render carbon monoxide harmless; that use of the device would prevent fatigue and promote mental alertness and good spirits, tranquilize those in severe pain as effectively as morphine, effectively counteract the substance in tobacco smoke which inhibits ciliary activity and thereby protect the smoking user from the danger of tobacco-smoke-induced lung cancer; that use of the device would stimulate the reticuloendothelial system of the body, a group of defense cells which marshal our resistance to disease.

DISPOSITION: 5–8–62. Default—delivered to the Food and Drug Administration.

7219. Cooler and humidifier device. (F.D.C. No. 47409. S. No. 34–959 T.)

QUANTITY: 54 devices at Minneapolis, Minn.

SHIPPED: 9–28–61 and 11–21–61, from Little Rock, Ark., by Essick Manufacturing Co.

LABEL IN PART: (Device) "Marvelaire * * * Marvelaire Cooler Company."

ACCOMPANYING LABELING: Leaflets reading in part "Marvelaire New Multi-Purpose Portable Humidifier" and "Marvelaire Portable Hey Now!"

RESULTS OF INVESTIGATION: The article appeared to be a portable unit designed to be a combination air purifier, humidifier, and cooler. The principal components consisted of a filter, air blower wheels, water recirculating pump, and water reservoir.

LIBELED: 4–4–62, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for doing away with, and preventing annoyance of, sore throat and other respiratory conditions; and banishing irritation of nose and throat membranes.

DISPOSITION: 5–10–62. Consent—claimed by Essick Manufacturing Co., Los Angeles, Calif., and released under bond for relabeling.

7220. **Vapozone device.** (F.D.C. No. 45319. S. No. 64–541 R.)

QUANTITY: 1 device at San Francisco, Calif., in possession of Mrs. Elizabeth Blumenthal, c/o Elysee Scientific Skin Studio.

SHIPPED: 6–23–60, from Karlsruhe, Germany, by Deutsch Nemectron Gesellschaft MBH.

LABEL IN PART: (Metal plate on device) "110 V Vapozone * * * Patent C. Ronzi * * * Karlsruhe, Germany."

ACCOMPANYING LABELING: A number of leaflets in the German language; a descriptive pamphlet in the German language; and a newspaper advertisement tear sheet entitled "Therapeutical Skin Salon Introducing Vapozone" prepared on instructions from the dealer.

RESULTS OF INVESTIGATION: The labeling and inspectors photographs indicated the article to consist of a high-voltage power supply, heater unit, and water tank for the production of steam and/or ozone. Steam was fed through a tube to an outlet nozzle which contained the electrode system for the production of ozone. The switching allowed for the use of steam alone or in conjunction with the ozone.

LIBELED: 1–13–61, N. Dist. Calif.; amended libel 1–16–61.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the device contained false and misleading representations that the article was an adequate and effective treatment for relieving or counteracting decubitus ulcers, gingivitis, bronchitis, asthma, dandruff, skin blemishes, blackheads, acne, and other disease conditions, as represented in the German literature.

DISPOSITION: 5–17–62. Default—delivered to the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 7161 TO 7220

PRODUCTS

[1] (7162, 7215) Seizure contested. Contains opinion of the court.
[2] (7187, 7212, 7214) Seizure contested.
[3] (7173, 7183, 7202) Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (7162, 7215) Seizure contested. Contains opinion of the court.
[2] (7187, 7212, 7214) Seizure contested.
[3] (7173, 7183, 7202) Injunction issued.
[4] (7164) Prosecution contested.
[5] (7172) Prosecution contested. Contains opinions and order of the courts. Injunction issued.

[1] (7162, 7215) Seizure contested. Contains opinion of the court.
[2] (7187, 7212, 7214) Seizure contested.
[3] (7173, 7183, 7202) Injunction issued.
[4] (7164) Prosecution contested.
[5] (7172) Prosecution contested. Contains opinions and order of the courts. Injunction issued.

[2] (7187, 7212, 7214) Seizure contested.
[3] (7173, 7183, 7202) Injunction issued.
[4] (7164) Prosecution contested.

[5] (7172) Prosecution contested. Contains opinions and order of the courts. Injunction issued.

U.S. GOVERNMENT PRINTING OFFICE:1963

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7221. (F.D.C. Nos. 44939, 44943/4 (3 criminal actions). S. Nos. 57-003 P, 57-027/8 P, 57-035/6 P, 57-041/2 P, 57-073 P, 57-075 P, 57-076/8 P, 72-331/2 P, 87-339/41 P.)

INFORMATIONS FILED: 2-24-61, S. Dist. Ga., Waycross Div., against **Robert Lee Clure and Mildred A. Clure, Homestead, Fla., James W. Altman, t/a Shell-Inn Truck Stop, Folkston, Ga., and Elmer Cecil Crews, Peter Crews, and Willie Lee Stevens (truck stop employees).**

On 3-1-61, S. Dist. Ga., Augusta Div., against Robert Lee Clure and Mildred A. Clure, Homestead, Fla., and **Emmett D. Nalley, Georgia Highway No. 47, near Washington, Ga.**

On 3-1-61, S. Dist. Fla., Jacksonville Div., against Robert Lee Clure and Mildred A. Clure, Homestead, Fla.

CHARGE: Waycross, Ga. Information. Prior to 4-27-59, and continuing to 10-28-59, Robert and Mildred Clure, James W. Altman, Elmer and Peter Crews, and Willie Lee Stevens conspired (count 1) to violate the Federal Food, Drug, and Cosmetic Act with respect to misbranding *amphetamine tablets* by unlawfully dispensing such drugs contrary to 503(b)(1), after shipment from outside the State of Georgia.

It was further a part of the conspiracy that Robert and Mildred Clure, would and did obtain from various suppliers, *amphetamine tablets* which had been manufactured outside the State of Georgia; that Robert and Mildred Clure, would and did supply to James W. Altman, *amphetamine tablets* which had been shipped in interstate commerce into the State of Georgia: and that Robert and Mildred Clure, James W. Altman, Elmer and Peter Crews, and Willie Lee Stevens would and did sell and dispense *amphetamine tablets* to customers without a prescription, contrary to 503(b)(1).

In furtherance, and to effect the objects of the conspiracy, Robert and Mildred Clure, James W. Altman, Peter and Elmer Crews, and Willie Lee Stevens did within the States of Georgia and Florida, commit various overt acts, among others the following:

1. On 4-27-59, Peter Crews, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *amphetamine sulfate tablets* without a prescription.

2. On 6-10-59, Elmer Cecil Crews, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* without a prescription.

3. On 6-10-59, Elmer Cecil Crews, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *amphetamine sulfate tablets* without a prescription.

4. On 7-15-59, Willie Lee Stevens, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *amphetamine sulfate tablets* without a prescription.

5. On 7-15-59, Willie Lee Stevens, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* without a prescription.

6. On 7-15-59, Peter Crews, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *amphetamine sulfate tablets* without a prescription.

7. On 7–15–59, Peter Crews, at the Shell-Inn Truck Stop, unlawfully dispensed to a Government agent, known to him as a truck driver, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* without a prescription.

8. On 10–26–59, Robert Lee Clure and Mildred A. Clure, had, at a truck stop, at Boulogne, Fla., a conversation with a Government agent, known to them as a truck stop employee, regarding the Shell-Inn Truck Stop.

9. On 10–28–59, James W. Altman, at a gasoline station near Folkston, Ga., on U.S. Highways Nos. 1, 23, and 301, unlawfully dispensed to a Government agent, known to him as a truck stop employee, *amphetamine sulfate tablets* without a prescription.

10. On 10–28–59, James W. Altman, at a gasoline station near Folkston, Ga., on U.S. Highways Nos. 1, 23, and 301, unlawfully dispensed to a Government agent, known to him as a truck stop employee, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* without a prescription.

In addition to the charge of conspiracy, between 4–27–59 and 10–28–59, it was alleged that *amphetamine sulfate tablets* (counts 2, 4, 5, 7, and 9) were dispensed 5 times, and *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* (counts 3, 6, 8, and 10) were dispensed 4 times, without a prescription.

Augusta, Ga. Information. Prior to 12–3–59, and continuing to 12–13–59, Robert and Mildred Clure, and Emmett D. Nalley conspired (count 1) to violate the Federal Food, Drug, and Cosmetic Act with respect to misbranding *amphetamine tablets* by unlawfully dispensing such drugs contrary to 503 (b) (1) after shipment from outside the State of Georgia.

It was a further part of the conspiracy that Robert and Mildred Clure would and did obtain from various other persons *amphetamine tablets* which had been manufactured outside the State of Georgia: that Robert and Mildred Clure would and did supply to Emmett D. Nalley *amphetamine tablets* which had been shipped in interstate commerce into the State of Georgia; that Robert and Mildred Clure would refer to Emmett D. Nalley, prospective customers to whom *amphetamine tablets* would be dispensed without prescription; and that the defendants would and did sell and dispense *amphetamine tablets* to customers without a prescription, contrary to 503(b) (1).

In furtherance, and to effect the objects of the conspiracy, the defendants did within the States of Georgia and North Carolina commit various overt acts, among others, the following:

1. On 12–3–59, Robert and Mildred Clure had a conversation at a truck stop located on Route 49 near Concord, N.C., with a Government agent regarding Emmett D. Nalley.

2. On 12–13–59, Emmett D. Nalley, on his premises located near Washington, Ga., on Georgia Highway No. 47, unlawfully dispensed to a Government agent, *dextro-amphetamine sulfate tablets* without a prescription.

3. On 12–13–59, Emmett D. Nalley, on his premises as above, unlawfully dispensed to a Government agent, *tablets containing a mixture of amphetamine sulfate and phenobarbital* without a prescription.

4. On 12–13–59, Emmett D. Nalley, on his premises as above, unlawfully dispensed to a Government agent, *tablets containing a mixture of amphetamine sulfate and phenobarbital* without a prescription.

5. On 12–13–59, Emmett D. Nalley, on his premises as above, unlawfully dispensed to a Government agent, *dextro-amphetamine sulfate tablets* without a prescription.

6. On 12–13–59, Emmett D. Nalley, on his premises as above, unlawfully dispensed to a Government agent, *desoxyephedrine hydrochloride tablets* without a prescription.

In addition to the charge of conspiracy, it was alleged that, on 12–13–59, *tablets containing a mixture of amphetamine sulfate and phenobarbital* (counts 3 and 4) and *dextro-amphetamine sulfate tablets* (counts 2 and 5) were each dispensed twice and *desoxyephedrine hydrochloride tablets* (count 6) were dispensed once without a prescription.

Jacksonville, Fla. Information. On 10–26–59, at a truck stop on U.S. Highways Nos. 1, 23, and 301, near Boulogne, Fla., *amphetamine sulfate tablets* (count 1) and *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* (count 2) were each dispensed once without a prescription by Robert and Mildred Clure.

PLEA: Guilty by Emmett D. Nalley to all counts of the Augusta, Ga. Information; guilty by James W. Altman to all counts; by Peter Crews to counts 1, 2, 7, and 8; by Elmer Crews to counts 1, 3, and 4; by Willie Lee Stevens to counts 1, 5, and 6, of the Waycross, Ga. Information; guilty by Robert and Mildred Clure to all counts of all three Informations.

DISPOSITION: On 9–19–61, at Waycross, Ga., Robert and Mildred Clure were arraigned and plead to the charges in the Waycross, Ga. Information, and at the same time tendered pleas to the charges in the Augusta, Ga., and Jacksonville, Fla., Informations. The cases against Robert and Mildred Clure involving the Jacksonville, Fla., and Augusta, Ga., Informations were transferred by consent to Waycross, Ga. On 9–26–61, Robert Clure was placed on probation for a period of 5 years conditioned upon payment of a $10,000 fine within 30 days, and Mildred Clure was placed on probation for a period of 5 years, conditioned upon payment of a $5,000 fine within 30 days.

On 10–27–61, Robert Clure having failed to pay his fine within 30 days as provided by the terms of probation, the court revoked his probation and sentenced him to 3 years imprisonment.

On 12–5–61, at Augusta, Ga., Emmett D. Nalley was fined $750 and placed on probation for 5 years.

On 9–19–61, at Waycross, Ga., Peter and Elmer Crews and Willie Lee Stevens were each fined $250 and placed on probation for 3 years.

On 9–26–61, at Waycross, Ga., James W. Altman was placed on probation for a period of 5 years conditioned upon payment of a $1,000 fine within 30 days.

7222. (F.D.C. No. 44620. S. Nos. 3–260 P, 71–948 P.)

INDICTMENT RETURNED: 8–9–60, M. Dist. Ga., against **Howard Francis Davis, formerly t/a Davis Truck Stop, Loganville, Ga.**

CHARGE: On 11–6–59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 12–7–60, and at the conclusion of the testimony, the jury returned a verdict of guilty. On 12–7–60, the court fined the defendant $100 and placed him on probation for 2 years.

7223. (F.D.C. No. 44956. S. Nos. 87–108/11 P.)

INFORMATION FILED: 3–1–61, S. Dist. Fla., against **Mark C. Dorsey, Forest Park, Ga.**

CHARGE: On 12–8–59, *amphetamine sulfate tablets, tablets containing a mixture of amphetamine sulfate and phenobarbital* and *Dexedrine Spansule capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: On 4–21–61, after the case had been transferred to the Northern District of Georgia, Dorsey was sentenced to imprisonment for 1 year.

7224. (F.D.C. No. 45555. S. Nos. 5–624 R, 5–626 R, 5–628/9 R.)

INFORMATION FILED: 5–25–61, Dist. Md., against **Roy Graner, Baltimore, Md.**

CHARGE: Between 10–10–60 and 10–26–60, *amphetamine sulfate tablets* were dispensed twice, and *Seconal Sodium capsules* and a bag containing *Seconal Sodium capsules* and *Dexamyl capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: On 9–15–61, the defendant served a motion to dismiss the information. After argument was heard by the court on 3–2–62, the court denied the motion. On 5–17–63, Graner was sentenced to imprisonment for 1 year.

7225. (F.D.C. No. 48153. S. No. 89–441 T.)

INFORMATION FILED: 10–18–62, E. Dist. Mich., against **John Kalagian, Detroit, Mich.**

CHARGE: On 7–21–62, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–31–62. Sentence of probation for 2 years.

7226. (F.D.C. No. 47852. S. No. 56–653 T.)

INFORMATION FILED: 9–10–62, E. Dist. Tex., against **Abie Anderson (a service station employee), Henderson, Tex.**

CHARGE: On 1–24–62, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–21–63. Sentence of 1 year suspended and probation for 2 years.

7227. (F.D.C. No. 48166. S. Nos. 64–636 T, 64–638 T, 64–660 T, 87–911 T.)

INFORMATION FILED: 10–26–62, E. Dist. S.C., against **Hugh J. Ware, Charleston, S.C.**

CHARGE: Between 6–6–62 and 7–24–62, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–21–63. $250 fine, 12 months imprisonment suspended, and probation for 3 years.

7228. (F.D.C. No. 48165. S. Nos. 64–639 T, 87–912/14 T.)

INFORMATION FILED: 10–26–62, E. Dist. S.C., against **Wilburt M. Dennis, Charleston, S.C.**

CHARGE: Between 6–9–62 and 7–25–62, *amphetamine sulfate tablets* were dispensed twice and *amphetamine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–21–63. $500 fine, 18 months imprisonment suspended, and probation for 3 years.

7229. (F.D.C. No. 48177. S. Nos. 3–270 T, 4–601/7 T.)

INFORMATION FILED: 12–11–62, E. Dist. Va., against **Joe W. Clark, t/a Sid's Bar-B-Q, South Hill, Va., and Claude Wilson (an employee).**

CHARGE: Between 12–12–61 and 2–13–62, *amphetamine sulfate tablets* were dispensed 8 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court without a jury and on 1–24–63, the court rendered a verdict of guilty on 4 counts of the information and not guilty on the other 4 counts. On 2–1–63, each defendant was given a sentence of 3 years in jail which was suspended, and was placed on probation for 3 years.

7230. (F.D.C. No. 48174. S. Nos. 16–222/3 T, 16–226 T, 16–801 T.)

INFORMATION FILED: 12–12–62, S. Dist. Ohio, against **Darnell Pugh, Dayton, Ohio.**

CHARGE: Between 10–14–61 and 12–12–61, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–31–63. Probation for 2 years.

7231. (F.D.C. No. 47876. S. No. 28–407 T.)

INFORMATION FILED: 10–10–62, Dist. Kans., against **Lloyd M. Parkinson, Topeka, Kans.**

CHARGE: On 10–11–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–5–63. Probation for 1 year.

7232. (F.D.C. No. 47887. S. Nos. 18–770/1 T.)

INDICTMENT RETURNED: 9–25–62, N. Dist. Tex., against **Hillard E. Bell, t/a Bell's Apco Station, Bowie, Tex.**

CHARGE: On 12–4–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–18–63. Probation for 1 year.

7233. (F.D.C. No. 48183. S. Nos. 27–326 T, 27–328 T, 29–265 T, 59–362 T, 59–366 T.)

INFORMATION FILED: 1–14–63, S. Dist. Iowa, against **Roy D. Richmond and Gearold M. Landtiser (partners in the partnership of the R & L Truck Stop), Bloomfield, Iowa.**

CHARGE: Between 2–1–62 and 6–6–62, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty by Richmond to 3 counts of the information and by Landtiser to 2 counts.

DISPOSITION: 4–1–63. Each individual fined $100, plus costs, given a suspended sentence of 4 months in jail, and placed on probation for 1 year.

7234. (F.D.C. No. 47081. S. Nos. 46–003/4 R.)

INFORMATION FILED: 10–31–62, W. Dist. N.C., against **Clyde William Ballard and Lula Knight Hall, Charlotte, N.C.**

CHARGE: On 3–30–61, *amphetamine sulfate tablets* and *tablets containing a mixture of amphetamine hydrochloride and phenobarbital* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–1–63. Ballard—probation for 3 years; Hall—1 year in prison suspended, and probation for 3 years.

7235. (F.D.C. No. 47342. S. Nos. 59–134/5 R, 59–142/3 R.)

INFORMATION FILED: 10–31–62, W. Dist. N.C., against **Ray Cameron Bishop, Charlotte, N.C.**

CHARGE: Between 3–17–61 and 3–21–61, *amphetamine sulfate tablets* were dispensed 3 times and *tablets containing a mixture of amphetamine hydrochloride and phenobarbital* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–1–63. $200 fine, sentence of 12 months in jail suspended, and probation for 3 years.

7236. (F.D.C. No. 48204. S. Nos. 38–421/2 T.)

INFORMATION FILED: 2–25–63, N. Dist. Miss., against **Fred Davis, t/a Fred Davis Truck Stop, Tupelo, Miss., and Elle Hugh Standifer (an employee).**

CHARGE: Between 1–24–62 and 1–25–62, *amphetamine sulfate tablets* were dispensed once by Fred Davis and once by Elle Hugh Standifer, without a prescription.

PLEA: Guilty.

DISPOSITION: 4–26–63. Davis—$200 fine and probation for 2 years; Standifer—probation for 2 years.

7237. (F.D.C. No. 47098. S. No. 39–411 T.)

INFORMATION FILED: 5–3–62, Dist. N.J., against **Michael C. Boyd, Newark, N.J.**

CHARGE: On 9–13–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–26–63. Sentenced to the custody of the Attorney General for an indeterminate term under the Federal Youth Correction Act.

7238. (F.D.C. No. 47101. S. No. 39–409 T.)

INFORMATION FILED: 5–3–62, Dist. N.J., against **Frank G. Masino, Newark, N.J.**

CHARGE: On 8–29–61, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case went to trial before the court and jury on 3–26–63, and was concluded 3–27–63, with a verdict of guilty by the jury. On 5–3–63, the defendant was sentenced to the custody of the Attorney General for an indeterminate time under the Federal Youth Correction Act.

7239. (F.D.C. No. 48195. S. Nos. 55-098/100 T.)

INFORMATION FILED: 12-7-62, M. Dist. N.C., against **Donald E. Wilhelm, of Winston-Salem, N.C.**

CHARGE: On 5-10-62, *amphetamine sulfate tablets* were dispensed once and *tablets containing a mixture of amobarbital and dextro-amphetamine sulfate* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5-7-63. Sentence of 1 year in prison.

7240. (F.D.C. No. 45556. S. No. 5-630 R.)

INFORMATION FILED: 5-21-61, Dist. Md., against **Bernard Kline, t/a North Gay Patent Medicine Store, Baltimore, Md.**

CHARGE: On 10-28-60, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 5-13-63, the case came on for trial before the court without a jury. On 5-14-63, the court found the defendant not guilty.

7241. (F.D.C. No. 47838. S. Nos. 39-620 R, 46-083 T.)

INFORMATION FILED: 8-9-62, E. Dist. Ill., against **Adolph J. Voigt, t/a Voigt's Cafe & Service, Olmsted, Ill.**

CHARGE: Between 4-21-61 and 12-4-61, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4-30-63. $200 fine, plus costs, and probation for 2 years.

7242. (F.D.C. No. 48175. S. Nos. 24-921/3 T, 24-926 T.)

INFORMATION FILED: 1-10-63, N. Dist. Ind., against **William E. Tolen, Lafayette, Ind.**

CHARGE: Between 12-6-61 and 2-7-62, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5-16-63. Suspended sentence of 6 months imprisonment, and probation for 1 year.

7243. (F.D.C. No. 48180. S. No. 89-141 T.)

INFORMATION FILED: 4-24-63, W. Dist. Pa., against **Joseph O. Errigo, t/a City Drug Store, Curwensville, Pa.**

CHARGE: On 8-7-62, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5-20-63. $500 fine, plus costs, and probation for 2 years.

7244. (F.D.C. No. 48205. S. Nos. 59-888/97 T.)

INFORMATION FILED: 11-30-62, N. Dist. Ala., against **Luke Taylor, Cullman, Ala.**

CHARGE: Between 8-29-62 and 9-9-62, *amphetamine sulfate tablets, desoxyephedrine hydrochloride tablets,* and *methamphetamine hydrochloride tablets* were dispensed 10 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–10–63. Jail sentence of 6 months and 1 day and probation for 2 years.

7245. (F.D.C. No. 39194. S. Nos. 51–539 M, 58–801/2 M.)

INFORMATION FILED: 9–14–56, Dist. Colo., against **Howard R. Marshall, Denver, Colo.**

CHARGE: Between 4–23–56 and 5–1–56, *dextro-amphetamine sulfate tablets* (counts 1 and 3) were dispensed twice and *pentobarbital sodium capsules* (count 2) were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 9–19–57. Before the Government's first witness had finished his testimony, one of the jurors informed the court that he was personally acquainted with the witness. The court thereupon declared a mistrial, and set the case down for a new trial on 9–25–57.

At the conclusion of the testimony on 9–30–57, the court granted defendant's motion for a directed verdict of acquittal on count 2, after which the jury returned a verdict of guilty on counts 1 and 3 of the information.

On 10–25–57, the court denied defendant's motion for a new trial and his motion for arrest of judgment and sentenced him to 6 months in jail. The defendant appealed to the United States Court of Appeals for the Tenth Circuit and, on 7–22–58, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court (258 F. 2d 94):

LEWIS, *Circuit Judge:* "Appellant was convicted on two counts of an information charging violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. 301 et seq. The principal issues before us spring from appellant's contentions that as a matter of law the defense of entrapment was established and that he was prejudiced beyond recall by newspaper accounts published during the course of his trial. Other errors assigned question the jurisdiction of the court and the sufficiency of the evidence to support the verdicts.

"The alleged entrapment centers around the activities of Robert E. Keating, an inspector for the United States Food and Drug Administration and an uncontroverted witness for the prosecution. Keating first met appellant in Denver, Colorado on April 18, 1956. The introduction of the two men was made at appellant's apartment by mutual friends, was purely social in form and did not disclose Keating's official employment. The conversation at this initial meeting was casual and general. On April 23, Keating returned to appellant's apartment and again visited with appellant and his wife. After some further social talk, Keating stated that he was driving to Dallas, Texas that evening and requested from appellant some 'stay-awake' pills to help him in the traveling. Appellant replied that Keating should obtain and take some No-Doz[1] tablets and drink coffee. Keating replied that he had tried No-Doz and coffee without obtaining the desired effect and wanted something different. Appellant repeated his recommendation and the conversation was then diverted into other subjects. After Keating left the apartment he was hailed by appellant and handed a package containing five tablets and two capsules. Appellant stated that the tablets were to be used if Keating became sleepy while driving and that the capsules should be taken if he was nervous after arriving in Dallas. Chemical analysis of the tablets established them to be dextro-amphetamine sulfate, a drug within the meaning of 21

[1] No-Doz is a patented product sold freely over-the-counter.

U.S.C.A. 353(b)(1)(B)[2] and within the prohibition of unlicensed dispensing under 21 U.S.C.A. 331(k).[3]

"On May 1, Keating again called on appellant, stating that he had 'gotten along very well' on the Dallas trip and would like a hundred or so of each of the drugs for a trip to be made to Los Angeles upon the following day. Appellant replied that he would have to go to the drugstore, refused Keating's suggestion that they go together, and told Keating to return later. This he did and was handed two vials containing 50 tablets and 24 capsules later analyzed as the prohibited drug. Keating paid appellant $15 upon this occasion.

"It is undisputed that all of Keating's representations relative to his identity, occupation, trips and use of drugs were entirely false and that upon each occasion the atmosphere of social friendship was created by conversation unrelated to the subject of 'stay-awake' tablets.

"The defendant offered no evidence. The issue of entrapment was submitted to the jury upon instructions not here questioned and the defense was rejected by conviction. Appellant urges that the court should have ruled as a matter of law that entrapment was established.

"The fountainhead rule and philosophy of entrapment was set out in *Sorrells* v. *United States*, 287 U.S. 435, 53 S. Ct. 210, 77 L. Ed. 413, and very recently debated in *Sherman* v. *United States*, ____ U.S. ____, and *Masciale* v. *United States*, —— U.S. —— ,both decided May 19, 1958. In *Sherman*, the court in reviewing the undisputed testimony of a Government witness unanimously concluded that the trial court was required under the circumstances therein to direct a verdict effectuating the defense of entrapment as a matter of law. The order of reversal set aside a verdict of a jury which had considered and rejected entrapment as a defense submitted to its consideration under instruction of the court. Since the instant case, as *Sherman*, involves only consideration of the undisputed testimony of a Government witness with no issue of credibility involved we conclude that submission of the issue of entrapment to the jury was improper. However, such submission could not prejudice appellant, in fact could but give him an unwarranted advantage, unless a directed verdict was required as a matter of law. A comparison of the activities of Keating with those of the informer in *Sherman*, where entrapment was established as a matter of law, and with those of the government agent in *Masciale*, where the court held entrapment not so established, shows the latter case to be persuasive.

"In *Sherman*, the Government informer met the defendant at a doctor's office where both were apparently being treated for narcotics addiction. They discussed over a period of time their difficulties in overcoming their habits and finally the informer confessed that he was unable to do so, begging the defendant to help him find a source of supply. Only after a number of repetitions of the request did the defendant finally procure the drug for his acquaintance. The result of this conduct was that the defendant himself returned to the use of narcotics. Emphasis is placed upon the fact that the Government played upon the known weaknesses of the defendant and that the crime resulted from the 'creative activity' of the law enforcement officials. Sec. 287 U.S. at 441, 451.

"In *Masciale*, the defendant was introduced to a Government agent by an informer who did not reveal the agent's capacity with the Government. The agent solicited the defendant for an introduction to a supplier of heroin. The court noted that the factual situation was such as to allow an inference that the defendant needed no persuasion to commit the crime.

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[2] 21 U.S.C.A. 353(b)(1). "A drug intended for use by man which—
* * *
(B) because of its toxicity or other potentiality for harmful effect or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug . . .
(C) . . . shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug. . . . The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed an act which results in the drug being misbranded while held for sale."

[3] 21 U.S.C.A. 331. "The following acts and the causing thereof are hereby prohibited:
* * *
(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

"Although in our case the activities of Keating consisted of artifice and deceit to lay a trap for defendant we believe the activities of the Government to be well within allowable limits. The law will protect the innocent from being led to crime through the activities of law enforcement officers, *Sherman* v. *United States*, *supra*, but it will not protect the guilty from the consequences of subjectively mistaking apparent for actual opportunity to safely commit crime. *Sorrells* v. *United States*, *supra*; *Archambault* v. *United States* (10 Cir.) 224 F. 2d 925.

"During the course of the trial two articles of a reckless nature were published in local newspapers covering matters far removed in time and place from a factual report of the trial occurrence. Six of the jurors read one of the articles and two of the six had read both. The trial court separately interviewed, in the presence and with the assistance of counsel, each of the jurors and thereafter denied a motion for mistrial. Each of the jurors indicated the articles would in no way influence his verdict.[4]

"It is conceded that a motion for a mistrial is addressed to the sound discretion of the trial judge, and whether it should be granted depends upon all of the circumstances in the case, *United States* v. *Carruthers* (7 Cir.) 152 F. 2d 512; *Marson* v. *United States* (6 Cir.) 203 F. 2d 904; *Webb* v. *United States* (10 Cir.) 191 F. 2d 512. The mere appearance of articles concerning the trial cannot compel a new trial, for the defense may at times be aided rather than hindered or the report may only convey to jurors that which they had heard the previous day in court or amount to fair comment thereon. *Miller* v. *Commonwealth of Kentucky* (6 Cir.) 40 F. 2d 820; *Klose* v. *United States* (8 Cir.) 49 F. 2d 177; *United States* v. *Pisane* (7 Cir.) 193 F. 2d 355. A cautionary instruction against prejudice or consideration of evidence beyond that presented in the courtroom has been held in such instances to be sufficient safeguard for defendant's rights.

"It is true that in certain instances the probable influence of newspaper publicity is so obvious that instructions by the court cannot be held to have preserved inviolate defendant's rights to a fair trial before an unbiased jury. See concurring opinion of Justices Jackson and Frankfurter, *Shepherd* v. *State of Florida*, 341 U.S. 50, 71 S. Ct. 549, 95 L. Ed. 740; *Griffin* v. *United States* (3 Cir.) 295 F. 437. But the difficulties of ever obtaining a jury completely unknowing and hence presumably unprejudiced in this day of wide coverage and circulation of newspapers presents a very real problem in the administration of justice. For this reason, some courts have been led to holding that to secure a reversal on this ground the defendant must demonstrate that

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[4] Typical of the responses received by the court is that of the juror Bottinelli.

"The Court: Morning, Mrs. Bottinelli, sit down right there. What I am inquiring about, Mrs. Bottinelli, are a couple of newspaper articles about this case, one of them appeared in the Post last night, and one of them in the News this morning. Did you read either one of these pieces?

Mrs. Bottinelli: Yes. I did, I read the one in the News.

The Court: The one in the News this morning?

Mrs. Bottinelli: Yes.

The Court: Did anything you read in that item prejudice you in any way against the defendant?

Mrs. Bottinelli: No, I would try to be as fair as I could.

The Court: Would what you read influence you in any way in reaching a verdict on the case?

Mrs. Bottinelli: No.

The Court: You could lay that out of your mind entirely and decide the case on the evidence you hear from the witness stand?

Mrs. Bottinelli: The evidence I've got to understand is whether he sold the medicine, so that would have nothing to do from this.

The Court: You would decide that from the evidence in the courtroom?

Mrs. Bottinelli: Yes, and not the rest.

The Court: You wouldn't have in mind this article you read in the newspaper whether he is guilty or innocent, is that right?

Mrs. Bottinelli: That's right.

The Court: Do any of you want to ask any further questions? All right, Mr. Francis.

Mr. Francis: I realize you want to be as fair as possible and certainly we would not have this jury if we didn't think every member was fair. Do you feel in your heart and without restraint that if you were in the defendant's position, that is to say, sitting where Mr. Marshall is sitting, and your own mind is as it is now as a result of having read the paper, that you could still feel that you could absolutely, impartially listen to the case and bring in a verdict?

Mrs. Bottinelli: Yes, I think I could.

Mr. Francis: Fine, thank you very much.

The Court: Thank you very much."

the failure to declare a mistrial under such circumstances was prejudicial to him, *Gicinto* v. *United States* (8 Cir.) 212 F. 2d 8, cert. den. 348 U.S. 884; *United States* v. *Carruthers, supra.*

"Had the instant trial been to the court alone it would be unquestioned that the court would be capable of and would divorce the extraneous matters from his mind and be perfectly free to continue with the trial. The care with which the trial court explored the knowledge and feeling of the individual jurors indicated to him that each juror was similarly qualified to proceed without prejudice. We cannot say the trial court abused its discretion in accepting as true the solemn statements of the individual jurors that no improper influence would carry over into their deliberations. See *United States v. Postma* (2 Cir.) 242 F. 2d 488. Strengthening our view that the trial court did not err in denying a mistrial is the completed record of the trial for, as stated in *Kotteakos v. United States*, 328 U.S. 750, 66 S. Ct. 1239, 90 L. Ed. 1557:

> In the final analysis judgment in each case must be influenced by conviction resulting from examination of the proceedings in their entirety, tempered but not governed in any rigid sense of stare decisis by what has been done in similar situations. Necessarily the character of the proceeding, what is at stake upon its outcome, and the relation of the error asserted to casting the balance for decision on the case as a whole, are material factors in judgment. 328 U.S. at 762.

"Here no affirmative defense was offered, neither the appellant nor a witness for him testified in his behalf; he was content to rely upon the hope of a failure of proof by the prosecution. The evidence was uncontroverted that he committed the crime and his contention that he was entitled to go to the jury on evidence of entrapment appearing in government testimony was, as we have held, without merit. Under all of the circumstances of the case, therefore, a jury properly instructed and acting in accordance with its duty could but return a verdict of guilty. We find no area for prejudice to occupy, even if it existed.

"Appellant's other contentions require little discussion. Asserting in the alternative that the Federal Court had no jurisdiction to try this offense because the drug, although shown to have traveled in interstate commerce, was no longer within federally protected traffic or that Congress constitutionally lacked the power to grant such jurisdiction, appellant cites the controlling case of *United States* v. *Sullivan*, 332 U.S. 689, 68 S. Ct. 331, 92 L. Ed. 297. Both propositions were settled in that case contrary to appellant's position on facts sufficiently similar to preclude argument.

"21 U.S.C. 331(k) makes it an offense to do any act with respect to a drug which results in its being misbranded while the article is held for sale *after shipment in interstate commerce.* The Supreme Court in the *Sullivan* case refused to give a restrictive interpretation to the statute because Congress intended to give protection to the ultimate consumer from the moment of the introduction of a drug into interstate commerce to the time of final delivery, regardless of intermediate intrastate transactions. It was there held that the Act as thus construed does not exceed the constitutional power of Congress under the Commerce Clause or invade the powers reserved to the states.

"The prosecution's case showed that the dextro-amphetamine sulfate tablets were manufactured in New York and that they were ultimately dispensed by appellant in Colorado. Apparently in this, as in most cases, it was impossible to trace the route taken in interstate commerce or to show that appellant received them from an interstate sale, but under the language of the statute and the interpretation of the Supreme Court, intervening sales are immaterial. *Archambault* v. *United States, supra.*

"Appellant finally argues that the proof that the drugs were manufactured in New York was incomplete, basing his argument on the fact that the tablets were compared for identification purposes with similar tablets previously collected from various manufacturers by the laboratory of the Food and Drug Administration. However, this comparision with the 'reference collection' was only preliminary and the investigation was concluded at the plant of the New York pharmacal company where identification both chemical and physical was made by the testifying witness. There is no merit in appellant's contention that the fact of interstate shipment was not adequately proved.

"AFFIRMED."

MURRAH, *Circuit Judge.* Dissenting: "We all appreciate the necessity for maintaining the inviolability of jury trials and our inescapable duty to vouchsafe them in the administration of justice. And, we know that we can do so only by wholly disinterested jurors whose judgments are based only upon a consideration of competent proof produced in open court. See *Southern Pacific Co.* v. *Klinge*, 65 F. 2d 85; *Little* v. *United States*, 73 F. 2d 861; *Stone* v. *United States*, 113 F. 2d 70; *Briggs* v. *United States*, 221 F. 2d 636. We recently had occasion to re-emphasize our solicitude in this regard. *Consolidated Gas & Equipment Co.* v. *Clarence F. Carver et al.* (10 CA) ——— F. 2d ———. And see also *Rubenstein* v. *United States*, 227 F. 2d 638, cert. den. 350 U.S. 993. Our problem is to achieve this ideal in an environment where crime and violence are exploited by news media and jurors are likely to be exposed, and consciously or unconsciously influenced by the emotional impact of the exploitation. In earlier times juries were completely insulated from all outside contacts. In modern times, the rules have been relaxed to allow jurors to separate under appropriate admonition not to read news accounts of the case on trial or to discuss the case with anyone, or to allow anyone to discuss it with them. Jurors have been trusted to observe these admonitions, and our faith has, in the main, been vindicated. We have indulged in the assumption that mere opportunity for prejudice or even corruption is no proof of it. See *Holt* v. *United States*, 218 U.S. 245.

"The necessity for conducting trials in an environment where separated jurors are almost unavoidably exposed to news comment, has led some courts to accept the 'standard judicial hypothesis that cautioning instructions are effective' to eradicate the contaminating effect of inflammatory exposures, unless there is a 'clear and present danger' of the deprivation of a constitutionally protected fair trial. See Chief Judge Clark in *United States* v. *Leviton*, 193 F. 2d 848. See also *Reining* v. *United States*, 167 F. 2d 362; *United States* v. *Allied Stevedoring Corp.*, 241 F. 2d 925; *United States* v. *Postma*, 242 F. 2d 488; *Henslee* v. *United States*, 246 F. 2d 190. Many cases on the subject are collected in an Annot. 31 A.L.R. 2d 417.

"I agree with Judge Frank (dissenting in the *Leviton* case, p. 865) that 'trial by newspaper,' even in the very midst of irresponsible news comment, is neither inevitable nor tolerable. Without assaying to curb extraneous comment on trials, it is my belief that jurors, while engaged in the trial of a case, can be appropriately and conveniently insulated from exposure to public emotionalism, which often attends criminal cases. Emphatic admonitions by the trial court at the very outset of the trial against the reading of newspapers or listening to news media, would go a long way toward safeguarding the trial against insidious and inflammatory matters. The trial court is, to be sure, the first and best judge of what is calculated to contaminate the jury or may have the ineradicable effect of doing so. Appellate courts should interfere only when matters of judicial policy are involved. In my opinion, matters of policy affecting the administration of criminal justice is involved here and it is my duty to speak.

"Of course intrusions may be only trivial or innocuous and certainly curable by appropriate admonitions. It is important that mistrials or new trials not be granted for 'trifling reasons.' See *Southern Pacific Co.* v. *Klinge*, *supra*. They may not be calculated to or have the effect of unduly influencing a juror, either consciously or unconsciously. But the newspaper article to which some of the jurors in this case were exposed stated not only the developments in the courtroom, it went on to state categorically that the accused had a 'record of two previous felony convictions'; that while serving a forgery sentence in a state penitentiary, he had testified before a state legislative committee then studying new state drug laws; that he had told the committee of having practiced medicine with a twenty-five dollar diploma received through the mails; and had written and passed prescriptions for dangerous drugs. The other newspaper article to which some of the jurors were exposed related that the accused had been arrested with his wife; that she had been convicted on drug charges in the same court and sentenced to jail.

"Since the accused elected to stand mute and did not offer his character as a defense, these statements were inadmissible and manifestly prejudicial. See *Michelson* v. *United States*, 335 U.S. 469. Indeed, no attempt was made to inject these matters in the trial of the case, and the court would have doubt-

less dealt firmly with any attempt to do so. Recognizing the gravity of the matter, the court conducted a searching inquiry concerning the jurors' exposure to the newspaper articles elicited from each of the jurors who had read them a vow that he or she was uninfluenced thereby, and would try the case as if they had not read them. The inquiry was as careful and the responses as positive as one could expect, and if we are to take the jurors' conscientious word for their state of mind, we must assume that all extraneous knowledge of the accused's prior and damaging record was completely banished from the jurors' minds and did not influence their consideration of his only defense of entrapment. But, the 'naive assumption that prejudicial effects can be overcome by instructions to the jury * * * all practicing lawyers know to be unmitigated fiction.' See Jackson concurring in *Krulewitch* v. *United States*, 336 U.S. 440, 453.

"Without questioning the thoroughness of the judicial inquiry, or impuning the conscientiousness of the jurors' avowals, it is my firm conviction that no juror could try this accused on the issue of whether he was in fact induced by the Government to commit the act for which he was on trial as if they did not know that his past record and moral traits inclined him toward it. I cannot believe that the untrained human mind is capable of any such nice discriminations. It is too much to expect a juror, sensing the impropriety of having read an extraneous and prejudicial account of a case he is then trying, to admit any prejudicial effect.

"If the jury is yet to be the factual judge of the defense of entrapment and the predisposition of the accused rather than the conduct of the Government is to be the legal test, i.e. see *Sherman* v. *United States*, 356 U.S. 369; and *Masciale* v. *United States*, 356 U.S. 386, prior record and moral traits become of primary importance in the determination of that vital issue. For in cases like this where entrapment is the only defense, prior convictions of the same offense are to be sure the best evidence to show essential predisposition. This brings us face to face with Mr. Justice Frankfurter's warning of the 'Danger of prejudice in such a situation.' For, said he, 'The defendant must either forego the claim of entrapment or run the substantial risk that, in spite of instructions, the jury will allow a criminal record or bad reputation to weigh in its determination of guilt of the specific offense of which he stands charged.' Concurring, *Sherman* v. *United States*, *supra*, p. 382. The only escape from the dilemma is to commit the issue of entrapment to the court. But, so long as it remains a jury question, record and reputation to prove predisposition or lack of it must be relevant, competent and admissible. *Harbolt* v. *United States* (10 CA) decided April 24, 1958, ____ F. 2d ____. If so, such evidence ought certainly to be produced in open court with the traditional right of confrontation and cross examination. If they are to be excluded, as in this case, they ought not be permitted to seep into the jury room to poison the minds of the jurors on the vital issue which divides guilt and innocence. In sum, it is my view that if the extraneous matter disclosed in the newspaper articles is forbidden, it is ineradicably prejudicial. If it is competent and admissible, it ought to be imparted to the jury in open court. In any event, I would reverse for a new trial."

The defendant filed a petition for certiorari with the United States Supreme Court, which was granted, and, on 6–15–59, the following opinion was handed down by that court (360 U.S. 310):

PER CURIAM: "Petitioner was convicted of unlawfully dispensing a number of dextro-amphetamine sulfate tablets, a drug within the scope of 21 U.S.C. § 353(b)(1)(B), without a prescription from a licensed physician, which resulted in misbranding and violation of 21 U.S.C. § 331(k). The Court of Appeals affirmed, one judge dissenting, 258 F. 2d 94. The case is here on a petition for certiorari, 28 U.S.C. § 1254(1), which we granted because of doubts whether exposure of some of the jurors to newspaper articles about petitioner was so prejudicial in the setting of the case as to warrant the exercise of our supervisory power to order a new trial. 358 U.S. 892.

"Petitioner never took the stand; nor did he offer any evidence. A Government agent testified that he was introduced to petitioner as a salesman who had difficulty staying awake on long automobile trips and that on two occasions he obtained these tablets from petitioner. Petitioner asked the

trial judge to rule there was entrapment as a matter of law. The judge refused so to hold and submitted the issue of entrapment with appropriate instructions to the jury. Cf. *Masciale* v. *United States*, 356 U.S. 386. The Government asked to be allowed to prove that petitioner had previously practiced medicine without a license, as tending to refute the defense of entrapment. The trial judge refused this offer saying, 'It would be just like offering evidence that he picked pockets or was a petty thief or something of that sort which would have no bearing on the issue and would tend to raise a collateral issue and I think would be prejudicial to the defendant.'

"Yet during the trial two newspapers containing such information got before a substantial number of jurors. One news account said:

> 'Marshall has a record of two previous felony convictions.
>
> 'In 1953, while serving a forgery sentence in the State Penitentiary at McAlester, Okla., Marshall testified before a state legislative committee studying new drug laws for Oklahoma.
>
> 'At that time, he told the committee that although he had only a high school education, he practiced medicine with a $25 diploma he received through the mails. He told in detail of the ease in which he wrote and passed prescriptions for dangerous drugs.'

The other news account said:

> 'The defendant was Howard R. (Tobey) Marshall, once identified before a committee of the Oklahoma Legislature as a man who acted as a physician and prescribed restricted drugs for Hank Williams before the country singer's death in December, 1953.
>
> . . . . . .
>
> 'Marshall was arrested with his wife, Edith Every Marshall, 56, in June, 1956. She was convicted on the drug charges in Federal District Court here in November and was sentenced to 60 days in jail.
>
> 'Records show that Marshall once served a term in the Oklahoma penitentiary for forgery. There is no evidence he is a doctor, court attaches said.'

"The trial judge on learning that these news accounts had reached the jurors summoned them into his chamber one by one and inquired if they had seen the articles. Three had read the first of the two we have listed above and one had read both. Three others had scanned the first article and one of those had also seen the second. Each of the seven told the trial judge that he would not be influenced by the news articles, that he could decide the case only on the evidence of record, and that he felt no prejudice against petitioner as a result of the articles. The trial judge, stating he felt there was no prejudice to petitioner, denied the motion for mistrial.

"The trial judge has a large discretion in ruling on the issue of prejudice resulting from the reading by jurors of news articles concerning the trial. *Holt* v. *United States*, 218 U.S. 245, 251. Generalizations beyond that statement are not profitable, because each case must turn on its special facts. We have here the exposure of jurors to information of a character which the trial judge ruled was so prejudicial it could not be directly offered as evidence. The prejudice to the defendant is almost certain to be as great when the evidence reaches the jury through news accounts as when it is a part of the prosecution's evidence. Cf. *Michelson* v. *United States*, 335 U.S. 469, 475. It may indeed be greater for it is then not tempered by protective procedures.

"In the exercise of our supervisory power to formulate and apply proper standards for enforcement of the criminal law in the Federal Courts (*Bruno* v. *United States*, 308 U.S. 287; *McNabb* v. *United States*, 318 U.S. 332) we think a new trial should be granted.

"*Reversed.*

"MR. JUSTICE BLACK dissents."

In accordance with the foregoing opinion the case was retried before a jury in the United States District Court for the District of Colorado. The trial began on 4–12–60 and was concluded on 4–14–60, with the return by the jury of a verdict of guilty.

The defendant filed motions for judgment of acquittal and for a new trial; and, on 5–13–60, the court denied the new motions. On 5–20–60, the court sentenced the defendant to imprisonment for 1 year. The defendant appealed to the United States Court of Appeals for the Tenth Circuit, and, on 7–26–61, the following opinion was handed down by that court (293 F. 2d 561):

LEWIS, *Circuit Judge:* "Appellant has now been twice tried and twice found guilty by juries upon each of two counts of an information charging violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 301, et seq. This court's affirmance of the judgment of conviction obtained at the first trial, 258 F. 2d 94, was set aside because of extraneous events occurring during the course of that trial which irretrievably prejudiced appellant, 360 U.S. 310, 79 S. Ct. 1171, 3 L. Ed. 2d 1250. Such extraneous events (interference by newspapers) did not recur and the instant appeal is now presented to us upon issues substantially the same as the remaining grounds which we earlier considered and rejected and upon which review was sought in the Supreme Court but refused. 358 U.S. 892, 79 S. Ct. 153, 3 L. Ed. 2d 120. Appellant again challenges the sufficiency of the evidence to sustain conviction and again asserts that the court erred in refusing to hold that entrapment was established as a matter of law.

"The premise of this prosecution was an alleged violation of the prohibition set forth in 21 U.S.C.A. 353(b) [1] through the unlawful dispensing of the drug dextro-amphetamine sulfate. To prove the drug to be within the compulsion of the statute the Government relied upon the uncontradicted testimony of a number of expert witnesses who described in detail the danger of the indiscriminate use of the drug and the necessity of control through sale only by direction of a competent physician. Complaint is now made that such proof was made through testimony given largely in the present tense at time of trial (1960) and was incompetent to prove the commission of a crime occurring in 1956. We find no merit to the contention. The fair import of the testimony indicates that the effect of the drug upon the human body and upon human behavior is now, and always has been potentially harmful. Indeed, this fact was known to the appellant for he cautioned his buyer:

> 'Don't take them in larger doses because you will begin to get nervous and experience anxiety and get to grinding your back teeth . . .'

"Opinion evidence, given in the present tense, may indeed be incompetent to prove an earlier fact. Opinions change through additional learning or experience. The medical profession is undoubtedly more aware now than it was in 1956 of the dangers in the excessive or casual use of amphetamine. This knowledge, together with the discovery of other drugs having similar benefits but more moderate side effects, has led to the less frequent prescribing of amphetamine. But this development can give no comfort to appellant for the record indicates that in 1956 the drug was considered unsafe for indiscriminate use. One witness testified that the drug had been under prescription for ten or fourteen years.

"Our earlier opinion details the evidence relating to the claim of entrapment as given at the first trial, 258 F. 2d 94. The testimony at the present trial was substantially the same but did, upon cross examination, develop

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[1] 21 U.S.C.A. 353(b).
"(1) A drug intended for use by man which

* * *

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug. . . .

* * *

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

the further fact that appellant Marshall was physically disturbed at the time of the commission of the offenses. The record is silent as to the cause of Marshall's condition and there is nothing to indicate any factor beyond the inference of self-indulgence in drug or alcohol. No claim is made that the Government contributed to Marshall's condition and such condition can be no more than a single circumstance proper to consider in the course of events leading to the sale of the contraband drug. Certainly self-impairment of physical or mental ability cannot, alone, result in entrapment as a matter of law and cannot, alone, 'protect the guilty from the consequences of subjectively mistaking apparent for actual opportunity to safely commit crime.' *Marshall* v. *United States*, 258 F. 2d 94, 97.

"We again conclude that the evidence did not establish entrapment as a matter of law and that the issue, having been submitted to the jury upon instructions identical to those given in the first case, was considered without prejudice to appellant. The court's instructions were deemed 'appropriate' by the Supreme Court. *Marshall* v. *United States*, 360 U.S. 310, 311.

"Finally, appellant charges error in the trial court's refusal to allow challenges for cause to two Government employees called as prospective jurors. The ruling of the court was correct. A Government employee is not disqualified from sitting as a juror in a criminal case simply because of the generality of his employment. *Baker* v. *Hudspeth*, 10 Cir., 129 F. 2d 779, cert. den. sub nom. *Baker* v. *Hunter*, 317 U.S. 681; *United States* v. *Wood*, 299 U.S. 123, 57 S. Ct. 177, 81 L. Ed. 78.

"AFFIRMED."

The defendant filed a petition for writ of certiorari with the United States Supreme Court on 8–21–61, and, on 11–6–61, such petition was denied.

7246. (F.D.C. No. 46001. S. Nos. 3–747/55 R, 3–757/9 R, 4–571 R.)

INFORMATION FILED: 1–19–62, Dist. Md., against **Edward Michael Horvath, Anna Catherine Henninger, and Manuel K. Highkin, Baltimore, Md.**

CHARGE: The information alleged in count 1 that the defendants Horvath and Highkin did on 10–12–60, and continuing thereafter to on or about 11–21–60, conspire, combine, confederate, and agree together and with diverse other persons to commit offenses against the United States, namely, to dispense *dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, desoxyephedrine hydrochloride tablets, secobarbital sodium capsules, pentobarbital sodium capsules*, and *Ergoapiol capsules* contary to the provisions of 503(b) (1) while said drugs were held for sale after shipment in interstate commerce, thereby causing said drugs to be misbranded; and that it was a part of the conspiracy for the defendant, Highkin, to obtain quantities of the drugs in tablet and capsule form and to supply quantities of the drugs to Defendant Horvath, and that Defendant Horvath would supply quantities to the defendant, Henninger; and that the drugs would be sold by all 3 defendants without a physician's prescription.

It was alleged further that in furtherance of the conspiracy and to effect its objects the defendants committed the following overt acts: on or about 10–19–60, at approximately 1:50 a.m., Anna Catherine Henninger did, at a manufacturing plant at Baltimore, Md., in response to the request of a Government agent, refer the agent to the individual who supplied drugs to Anna Catherine Henninger, namely, Edward Michael Horvath; on or about 10–19–60, at approximately 1:55 a.m., Edward Michael Horvath had a conversation with a Government agent in regard to the sale of drugs to the agent; on or about 10–20–60, Edward Michael Horvath dispensed to a Government agent a number of *dextro-amphetamine sulfate tablets* without a prescription therefor; on or about 10–21–60, Edward Michael Horvath had a conversation with a Government agent in regard to the sale of drugs to the agent; on or about 10–22–60,

Edward Michael Horvath had a telephone conversation with a Government agent in regard to the sale of drugs; on or about 10–22–60, Edward Michael Horvath dispensed to a Government agent a number of *amphetamine sulfate tablets* without a prescription therefor; on or about 11–1–60, Edward Michael Horvath had a telephone conversation with a Government agent with respect to the sale of drugs to the agent; on or about 11–1–60, Edward Michael Horvath had a conversation with a man in a Nash Rambler bearing Maryland license plates registered in the name of Manuel K. Highkin; on or about 11–1–60, Edward Michael Horvath dispensed to a Government agent a number of *desoxyephedrine hydrochloride tablets* and a number of *amphetamine sulfate tablets* without a prescription; on or about 11–2–60, Edward Michael Horvath had a telephone conversation with a Government agent in regard to the sale of drugs; on or about 11–2–60, Edward Michael Horvath had a conversation with the defendant, Manuel K. Highkin; on or about 11–2–60, Edward Michael Horvath dispensed a number of *secobarbital sodium capsules* and a number of *pentobarbital sodium capsules* without a prescription; on or about 11–8–60, Edward Michael Horvath had a conversation with a Government agent; on or about 11–8–60, Edward Michael Horvath dispensed to a Government agent a number of *secobarbital sodium capsules* without a prescription; on or about 11–9–60, Edward Michael Horvath had a telephone conversation with a Government agent; on or about 11–9–60, Edward Michael Horvath caused to be dispensed to a Government agent a number of *Ergoapiol capsules* without a prescription; on or about 11–10–60, Edward Michael Horvath had two telephone conversations with a Government agent; on or about 11–21–60, Edward Michael Horvath had a telephone conversation with a Government agent; on or about 11–21–60, Edward Michael Horvath caused to be dispensed to a Government agent quantities of *dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, secobarbital sodium capsules,* and *pentobarbital sodium capsules,* without a prescription therefor.

The information alleged also (counts 2 to 15) that between 10–12–60 and 11–21–60, *dextro-amphetamine sulfate tablets* were dispensed 4 times, *amphetamine sulfate tablets* and *secobarbital sodium capsules* were each dispensed 3 times, *pentobarbital sodium capsules* were dispensed twice, and *desoxyephedrine hydrochloride tablets,* and *Ergoapiol capsules* were each dispensed once without a prescription.

PLEA: Guilty by Highkin and Horvath to all 15 counts; by Henninger to counts 2 and 3 involving the dispensing of *dextro-amphetamine sulfate tablets.*

DISPOSITION: 3–30–62. Highkin—$750 fine, plus costs, 3 months in prison, and 2 years probation; Horvath—$250 fine, plus costs, 3 months in prison, and probation for 2 years; Henninger—assessed costs and placed on probation for 1 year.

7247. (F.D.C. No. 48524. S. Nos. 678 T, 680 T.)

INFORMATION FILED: 4–11–63, N. Dist. Ga., against **James R. Timmons (a truck stop employee), Villa Rica, Ga.**

CHARGE: Between 6–8–62 and 6–19–62, *dextro-amphetamine sulfate tablets* and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5–20–63. $200 fine and probation for 2 years.

7248. (F.D.C. No. 48555. S. Nos. 661 T, 673 T, 76–912 T, 76–928 T.)

INFORMATION FILED: 5–3–63, E. Dist. S.C., against **Hammon Theodore Hilton (a truck stop employee), Summerton, S.C.**

CHARGE: Between 5–4–62 and 5–25–62, *dextro-amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5–20–63. Probation for 5 years.

7249. (F.D.C. No. 46696. S. No. 46–904 R.)

INFORMATION FILED: 9–21–62, E. Dist. Mich., against **Samuel Katz, t/a S.K. Drugs, Highland Park, Mich., and Murray K. Dressler (pharmacist).**

CHARGE: On 8–1–60, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–13–63. Katz—$500 fine and probation for 2 years; Dressler—probation for 2 years.

7250. (Inj. No. 370.)

COMPLAINT FOR INJUNCTION FILED: 2–1–60, S. Dist. Tex., against **Dr. Robert E. Lester, Willis, Tex.**

CHARGE: The complaint alleged that the defendant was a doctor of medicine who was engaged in the business of selling and dispensing *dextro-amphetamine sulfate tablets* and *amphetamine sulfate racemic tablets;* that he caused such drugs, while held for sale after shipment in interstate commerce, to be dispensed to persons with whom he had no bona fide relationship of physician and patient; and that the defendant, by causing the dispensing of such drugs to those persons, caused the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs.

DISPOSITION: On 2–1–60, the court entered a temporary restraining order enjoining the defendant against the acts complained of. On 2–10–60, the court entered a preliminary injunction against the defendant enjoining him from directly or indirectly dispensing and causing to be dispensed *dextro-amphetamine sulfate tablets, amphetamine sulfate racemic tablets* and any other drugs within the meaning of 503(b)(1), while held for sale after shipment in interstate commerce, unless there exists

(a) a bona fide relationship of physician and patient between the defendant and the person to whom any one of such drugs is to be dispensed; and

(b) a prescription for the drug which is to be dispensed to such person is written and held in file by the defendant.

7251. (F.D.C. No. 48155. S. Nos. 13–121 T, 13–123/24 T.)

INFORMATION FILED: 11–14–62, N. Dist. Ill., against **Sol Lapofski, t/a Lapofski Drug Store, Chicago, Ill.**

CHARGE: Between 10–19–61 and 12–4–61, *dextro-amphetamine sulfate capsules, amorbarbital-secobarbital sodium capsules,* and *Equanil capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6–21–63. $300 fine, plus costs.

7252. (F.D.C. No. 44635. S. Nos. 59–691/2 P, 59–694 P.)

INFORMATION FILED: 8–4–60, S. Dist. W. Va., against **Buford W. Adams (a truck stop employee), Hale's Gap, W. Va.**

CHARGE: Between 9–30–59 and 10–25–59, *amphetamine hydrochloride tablets, tablets containing a mixture of amphetamine sulfate and phenobarbital* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 1–23–61, the case came on for trial before the court and jury. On 1–24–61, the jury returned a verdict of guilty. On 4–11–61, Adams was sentenced to 1 year in prison.

7253. (F.D.C. No. 46694. S. Nos. 22–760 R, 22–830 R, 24–139 R, 85–779 R.)

INFORMATION FILED: 3–9–62, W. Dist. Mo., against **Save More Drug Stores, Inc., Raytown, Mo., and W. Gerald Berry and Bertrand L. Blann (pharmacists).**

CHARGE: Between 4–15–61 and 6–12–61, *Antabuse tablets* (2 counts) and *Nembutal capsules* (2 counts) were each dispensed twice without a prescription.

PLEA: Guilty by the corporation to 4 counts of the information; by Blann to 2 counts; and by Berry to 2 counts.

DISPOSITION: 5–25–62. Each defendant fined $200.

7254. (F.D.C. No. 47886. S. Nos. 20–529 T, 20–539/40 T.)

INDICTMENT RETURNED: 9–25–62, N. Dist. Tex., against **Harrell's Gaston Avenue Pharmacy, Inc., Dallas, Tex., Eldridge C. Harrell (president), Ernest N. Stayton (vice president), Thomas M. Chastain (pharmacist), and Ray Foster McCormick (pharmacist).**

CHARGE: Between 3–2–62 and 3–14–62, *Compocillin tablets* were dispensed twice and *Dexedrine Sulfate tablets* were dispensed once upon request for prescription refills without obtaining authorization from the prescriber.

PLEA: Nolo contendere by each defendant to 1 count.

DISPOSITION: 11–21–62. Each defendant fined $200.

7255. (F.D.C. No. 44296. S. Nos. 5–622/24 P.)

INFORMATION FILED: 5–2–60, Dist. Md., against **Ansel W. Braden, t/a Braden's Professional Pharmacy, Silver Spring, Md.**

CHARGE: Between 4–28–59 and 5–5–59, *Meticorten tablets* were dispensed twice upon request for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–9–60. $100 fine, plus costs.

7256. (F.D.C. No. 48140. S. Nos. 1–066/7 T, 1–075 T, 1–089/90 T, 1–486 T, 2–729 T, 2–751/2 T, 2–754 T.)

INFORMATION FILED: 10–30–62, N. Dist. Ga., against **Oswald H. Mimms (partner in Mimms Pharmacy), Norcross, Ga., and Marion Gordon Weatherby (pharmacist).**

CHARGE: Between 11–20–61 and 2–20–62, *Miltown tablets* were dispensed 6 times, *Equanil tablets* were dispensed 3 times, and *Gantrisin tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–12–62. Each defendant fined $250, and placed on probation for 2 years.

7257. (F.D.C. No. 41171. S. Nos. 76–927 M, 76–930 M, 77–205 M.)

INFORMATION FILED: On or about 5–17–58, N. Dist. Ga., against **Willard M. Drew, t/a Drew's Pharmacy, Cedartown, Ga.**

CHARGE: Between 7–23–57 and 8–5–57, *secobarbital sodium capsules* were dispensed 3 times upon request for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 6–13–58. $500 fine and probation for 2 years.

7258. (F.D.C. No. 46706. S. Nos. 52–761/2 R. 52–766/7 R.)

INFORMATION FILED: 10–18–62, W. Dist. Wis., against **Harold Krom, t/a Withee Drug Store, Withee, Wis., and Milton A. Krom (manager-pharmacist).**

CHARGE: Between 4–18–61 and 4–20–61, *Sterane* and *Sibol* were each dispensed once without an order from a licensed veterinarian, or adequate directions for use in their labeling; and between 4–28–61 and 5–4–61, *Equanil tablets* and *Dexedrine Sulfate tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–13–62. Harold Krom—$100 fine; Milton A. Krom—$400 fine.

7259. (F.D.C. No. 46703. S. Nos. 29–990 R, 29–993/4 R.)

INFORMATION FILED: 10–18–62. W. Dist. Wis., against **Bertelsen Pharmacies, Inc., t/a Bertelsen's College Pharmacy, River Falls, Wis., and Donald D. Aspenes (vice president and pharmacist).**

CHARGE: Between 3–3–61 and 4–5–61, *Sibol* was dispensed once and *Sparine Hydrochloride tablets* were dispensed twice without an order from a licensed veterinarian.

PLEA: Nolo contendere.

DISPOSITION: 11–13–62. Corporation—$100 fine; individual—$400 fine.

7260. (F.D.C. No. 46705. S. Nos. 52–771/2 R, 52–778 R, 52–780 R.)

INFORMATION FILED: 10–18–62, W. Dist. Wis., against **Harvey W. Weddig, t/a Weddig's Rexall Drug, Owen, Wis., and William M. George (pharmacist).**

CHARGE: Between 4–18–61 and 5–16–61, *streptomycin sulfate* was dispensed twice without a prescription; and *Sterane* and *Sibol* were each delivered once to the ultimate purchaser without an order from a licensed veterinarian and without labeling bearing adequate directions for use.

PLEA: Nolo contendere by Weddig to 4 counts involving all of the drugs, and by George to two counts involving the *streptomycin sulfate*.

DISPOSITION: 11–13–62. Weddig—$100 fine; George—$400 fine.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 7221 TO 7260

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1](7222, 7229, 7238, 7240, 7252) Prosecution contested.

[2](7245) Prosecution contested. Contains opinions of the Appelate Court and of the U.S. Supreme Court.

[3](7250) Injunction issued.

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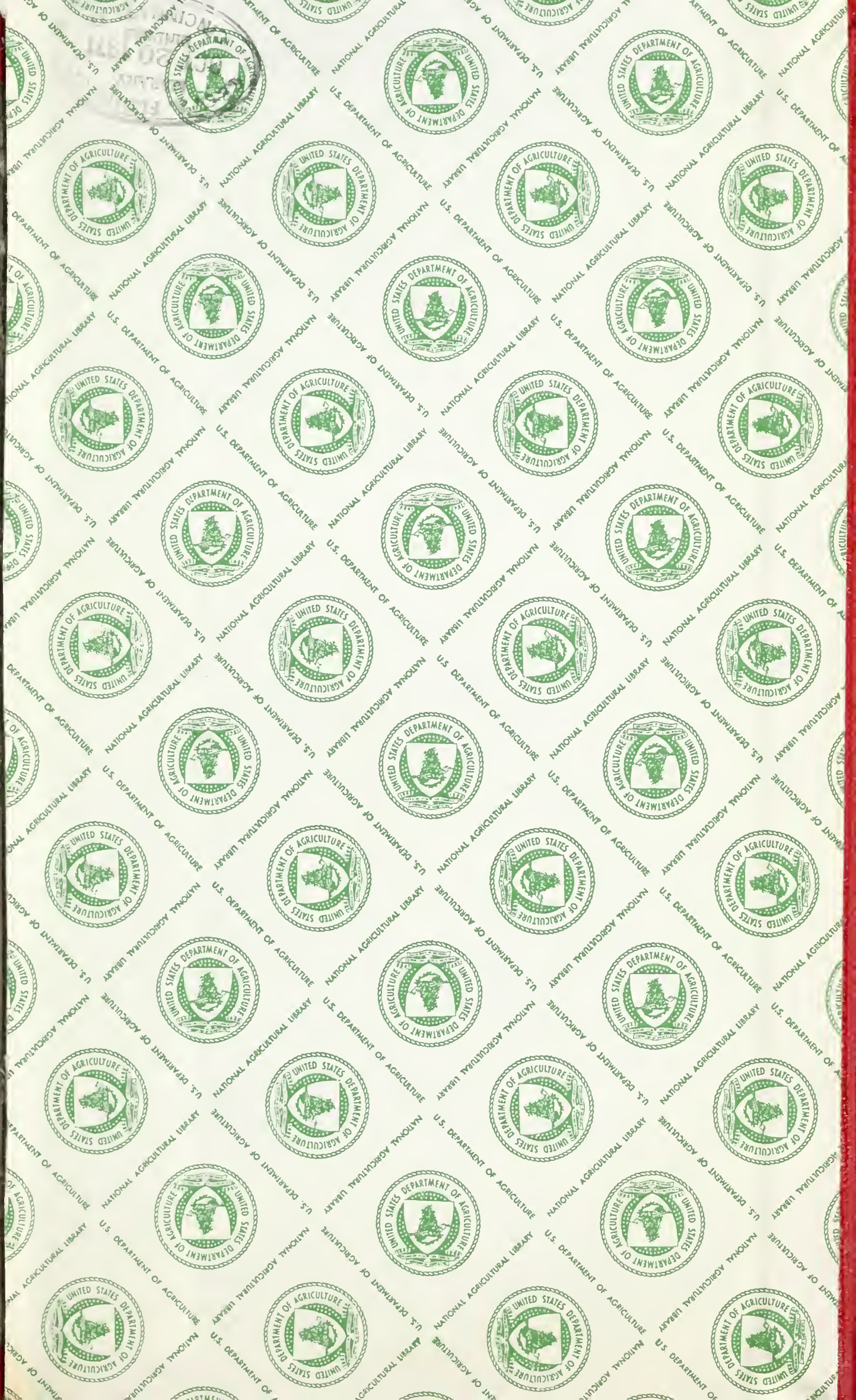
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